



**Council for Trade-Related Aspects of  
Intellectual Property Rights**

**MINUTES OF MEETING**

HELD IN THE CENTRE WILLIAM RAPPARD ON 13 FEBRUARY 2019

*Chairperson: H.E. Ambassador Dr Walter Werner (Germany)*

*Addendum*

The present document contains the statements made during the Council for TRIPS meeting held on 13 February 2019.

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\*A record of statements as delivered in the formal session of the Council. Some statements have been lightly edited as appropriate to ensure the consistency of presentation.

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## 1 NOTIFICATIONS UNDER PROVISIONS OF THE AGREEMENT

### 1.1 Japan

1. This delegation is pleased to inform the Council that Japan recently amended its Unfair Competition Prevention Act, Patent Act, and Trademark Act. The amendments have been notified to this Council in accordance with Article 63.2. The reference numbers are IP/N/1/JPN/U/2, IP/N/1/JPN/P/14 and IP/N/1/JPN/T/9., We would like to take this opportunity to briefly explain some major points about the amendments.

2. First, the Unfair Competition Prevention Act was revised to enhance regulation on acts of unfair competition that interfere with the technological restriction measures. For example, the revised Act newly covers regulations on the act of providing services of circumventing technological restriction measures to users.

3. Secondly, the Patent Act was revised to be compatible with the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (hereinafter CPTPP), in particular with adding a new provision regarding the extension of duration of patent rights. Concretely, due to the revision, the duration of patent rights has turned to be extendable if the establishment of a patent right is registered after the date either five years since filing, or three years since a request for examination, whichever is later. The new system will be applicable to patent filings after 10 March 2020.

4. Lastly, the Trademark Act was also revised to be compatible with the CPTPP, in particular with adding a new provision regarding the presumption of amount of damages. Specifically, the new provision enables a trademark holder to claim the damages with the presumption that it is the amount equivalent to the expenses which are normally required for the acquisition and maintenance of the trademark right.

5. The Government of Japan will continuously fulfil its obligation to ensure the accessibility and the transparency of the Japanese intellectual property system.

### 1.2 Chinese Taipei

6. The amendments to the Regulations Governing the Determination of Patent Term Extension and the Enforcement Rules of the Trademark Act were notified to the TRIPS Council on the 29 November 2018, contained in documents IP/N/1/TPKM/P/11 and IP/N/1/TPKM/T/9.

7. With regard to the Regulations Governing the Determination of Patent Term Extension, it is aimed at streamlining the application process. This means, for example, that in the case of a request for extension of the patent term based on a clinical trial or field test conducted in a foreign country, the document proving that the trial time has been claimed and approved for patent term extension by the foreign country will no longer be required.

8. As far as the Enforcement Rules of the Trademark Act are concerned, the Schedule attached to Article 19 - the list of goods and services - is now deleted. According to our understanding, this means that the Enforcement Rules of the Trademark Act will not anymore be subject to amendments in response to the updated versions of WIPO International Classification of Goods and Services.

### 1.3 Norway

9. The notifications from Norway contained in the mentioned documents include amendments made to the Designs Act, the Patent Regulations, the Regulations on Fees payable to the Norwegian Industrial Property Office and the Board of Appeal for Industrial Property Rights, the Trademarks Act, as well as a corrected translation of the Patents Act.

- The amendments to the Trademarks Act are due to the entry into force of the Penal Code (Act no 28 of 20 May 2005) and include updating provisions on criminal sanctions and correcting references to the Penal Code.

- The amendments to the Designs Act include a change in the provision on criminal sanctions and corrected references to the Penal Code. The provision in Section 54 concerning the priority between third party rights in a registered design is also amended.
- The amendments to the Patent Regulations concern provisions of a technical character complementing the changes made to the Patents Act (Act no. 9 of 15 December 1967) and the Act on Security Interests (Act no 2 of 8 August 1980) introducing the possibility of establishing security interests in patents and plant variety rights.
- The amendments also include provisions on the processing of applications for and handling of extensions of supplementary protection certificates for medicinal products for paediatric use.
- The amendments in the Regulation on Fees concern changes necessary for the introduction of the possibility to create security interests in patents and plant variety rights. The amendments include changes of a technical nature and introduces a fee for the extension of supplementary protection certificates for medicines for paediatric use.
- The translation of the Patents Act is updated, correcting errors in the previous translation.

#### 1.4 United States of America

10. The United States has notified three legal amendments: the Study of Classes Chasing Engineering and Science Success (hereinafter SUCCESS Act 2018) (IP/N/1/USA/P/15), Music Modernization Act (IP/N/1/USA/C/7), and the Marrakesh Treaty Implementation Act (IP/N/1/USA/C/8).

11. First, the SUCCESS Act 2018 amends the Leahy-Smith America Invents Act to extend by eight more years the authority granted to the USPTO to effectively adjust, with public input and oversight, the fees it charges for the services it provides to patent and trademark applicants. Extension of the authority helps ensure that those fee collections fully recover the costs of USPTO's operations and services provided to innovators. The law also provides for a report that identifies publicly available data on the number of patents annually applied for and obtained by women, minorities, and veterans, and small businesses owned by women, minorities and veterans, and includes legislative recommendations for how to increase participation in entrepreneurial activities and patenting by women, minorities, and veterans.

12. Next, the Orrin G. Hatch–Bob Goodlatte Music Modernization Act, or MMA, addresses the United States' determination that copyright law has not kept pace with changing consumer preferences and technological developments in the music marketplace. It was signed into law on 11 October 2018.

13. Title I of the MMA, or the Music Licensing Modernization Act, among other things, modifies the existing section 115 "mechanical" license for reproduction and distribution of musical works in phonorecords (which was previously obtained by licensees on a per-work, song-by-song basis).

- This Title establishes a new blanket license for digital music providers to engage in specific covered activities (namely, permanent downloads, limited downloads, and interactive streaming).
- Licensing of physical configurations (such as CDs, vinyl) will still operate on a per-work, individual song license, basis. Title I establishes a market-oriented "willing buyer, willing seller" rate standard that will apply to all licensees of musical works under the section 115 mechanical license.
- Also, under Title I of the MMA, the Register of Copyrights will designate an entity as the mechanical licensing collective to administer the blanket license and distribute collected royalties to songwriters and music publishers.
- The newly created mechanical licensing collective will be tasked with developing and maintaining a database of musical works and sound recordings, which will be publicly

available and is expected to become the most comprehensive database in the music industry.

- There will be a transition period to move to the new blanket license, allowing digital music providers to limit copyright infringement liability so long as the provider engages in good-faith, commercially reasonable efforts to identify and locate musical work copyright owners.
- The legislation also modifies the process for selecting federal district court judges to adjudicate rate-setting disputes regarding performance rights organizations that are subject to consent decrees with the Department of Justice.

14. Title II of the MMA, or the Classics Protection and Access Act, among other things, brings pre-1972 sound recordings partially into the federal copyright system by extending remedies for copyright infringement to owners of sound recordings fixed before 15 February 1972.

- The federal remedies for unauthorized use of pre-1972 sound recordings shall be available for 95 years after first publication of the recording, and are subject to certain additional periods, which provide varying additional protection for pre-1972 sound recordings, based on when the sound recording was first published.
- Title II applies a statutory licensing regime similar to that which applies to post-1972 sound recordings.
- It also establishes a process for lawfully engaging in non-commercial uses of pre-1972 sound recordings that are not being commercially exploited.
- Finally, Title II of the MMA applies certain existing limitations on exclusive rights and limitations on liability to uses of pre-1972 sound recordings, such as, sections 107, 108, 109, 110, 112 and 512.

15. Title III of the MMA, or the Allocation for Music Producers Act among other things, will allow music producers to receive compensation from royalties collected for uses of sound recordings under the section 114 statutory license.

16. The Marrakesh Treaty Implementation Act was signed into law on 10 October 2018. It revises the Copyright Act to meet the terms of the 2013 Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled.

17. The Marrakesh Treaty requires its contracting Members to create limitations and exceptions to copyright law that will make it easier for those with certain kinds of print disabilities to access printed works in accessible formats such as Braille and digital audio files.

18. The United States confirms that it deposited the US Marrakesh ratification materials with WIPO on 8 February 2019.

### **1.5 WTO Secretariat**

19. The Secretariat appreciates the opportunity to provide a further regular update to the TRIPS Council on the e-TRIPS project. Delegates will recall that the e-TRIPS project aims at streamlining and bringing up to date the information services the Secretariat provides for Members, while remaining fully within the framework established by the TRIPS Agreement itself and the decisions of this Council. It comprises three elements – first, a means of receiving TRIPS notification and review material, the e-TRIPS Notification Submission System (the e-TRIPS NSS); second, a complete Information Management System, now the backbone of our TRIPS information services; and, third, an e-TRIPS Gateway which will be integrated with the WTO website and provide a wide range of opportunities for delegates to access and make use of TRIPS information.

20. Today, we are pleased to announce that the first element, the e-TRIPS Notification Submission System (the e-TRIPS NSS) is now open and ready for your use.

### What is the e-TRIPS NSS?

21. The e-TRIPS NSS is an optional online tool for submitting:

- TRIPS notifications, such as newly passed laws and regulations relevant to TRIPS;
- TRIPS review materials, such as responses to the questionnaires established by the TRIPS Council; and
- TRIPS-related Reports, such as regular reports on technical assistance and measures for technology transfer filed by some Members and some international intergovernmental organizations.

22. Traditional methods of notifying to the TRIPS Council will, of course, remain available. However, we have endeavoured to make the e-TRIPS NSS easy to use, and trust that it will become the preferred means for submitting notifications, review materials and reports to the Council for TRIPS. As we approach 25 years of operation of TRIPS notification and review processes, we are very conscious that it can be difficult to track existing notifications and to update submissions accordingly. We are also conscious that there are some extensive gaps in coverage of material provided. Our immediate emphasis, therefore, is on supporting delegates and capital-based officials to become familiar with this tool and to assist them in its practical use.

### Next STEPS

23. In the coming weeks, therefore, the Secretariat will send an email to all Missions to the WTO with guidance on how to access and use the e-TRIPS NSS. User names and passwords for using the system will be provided to delegations. We will also provide a user guide, which will explain how the e-TRIPS NSS works, and what can (and cannot) be submitted through the e-TRIPS NSS. In addition, delegations will also be able to access an online training environment, which is, in effect, a test site reproducing all of the functions of the e-TRIPS NSS. Any practice entries made when using this training tool will go no further than the test site and will not, of course, be formally notified to the TRIPS Council.

24. We are also available at any time to demonstrate the NSS to any interested delegations, or to assist in its use in submitting notifications and review materials.

25. Additionally, on the margins of the Council meeting in June, the Secretariat will provide an informal training session for interested delegations on how to use the new system.

26. The e-TRIPS NSS will be available in the three official WTO languages. The initial version that will be made available in the coming weeks will, however, only be available in English. The site is currently being translated and it will be made available in French and Spanish as soon as possible.

27. We are deeply grateful for the feedback and collaboration of many delegates who have helped to shape and refine this new tool in line with your actual practical requirements, during an extended development process. This initiative truly could not have come to fruition without this valuable input. We continue to welcome any feedback on how you think the e-TRIPS NSS could be improved in the light of practical experience.

### The broader e-TRIPS Gateway

28. I would like to turn now to a brief update on the broader e-TRIPS Gateway – in other words, the online information portal that will allow you to search and extract the full range of TRIPS information managed by the Secretariat. Work is progressing steadily. As reported earlier, we will be engaging with delegates and other stakeholders on the design and layout of this Gateway, again with a view to building it around the practical needs and requirements of Members. We hope to provide a more substantive update at the June meeting, including information on an initial release version for trial by delegations, and look forward to your guidance on this stage of the project as well.

## 2 REVIEW OF NATIONAL IMPLEMENTING LEGISLATION

29. No statements were made under this agenda item.

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### **3 REVIEW OF THE PROVISIONS OF ARTICLE 27.3(B)**

### **4 RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY**

### **5 PROTECTION OF TRADITIONAL KNOWLEDGE AND FOLKLORE**

#### **5.1 India**

30. There is no change in India's position on the issues of review of the provisions of Article 27.3(b), relationship between the TRIPS Agreement and the CBD, and protection of traditional knowledge and folklore. However, India would take this opportunity to highlight some of the important points from our last submission. India is an ancient civilization with a rich body of traditional knowledge associated with biological resources. In India's case, this traditional knowledge is both coded, as in the texts of Indian systems of medicine, such as Ayurveda, Unani and Siddha; and non-coded, which exists in the oral undocumented traditions. India is also amongst top 20 identified mega diverse countries in the world.

31. Countries have adopted various methods to protect traditional knowledge and associated genetic resources at the national level. However, in the absence of an enforceable international regime, such domestic/national regimes on their own cannot address misappropriation of existing knowledge in foreign patent offices and biopiracy.

32. Therefore, it has been one of our long-standing demand that there should be an international enforceable regime that makes patent offices the checkpoint to contain such misappropriation. As in fact, patents should not be granted for existing traditional knowledge and associated genetic resources, and where traditional knowledge and associated genetic resources form the basis of scientific development, patent applications must disclose source or origin of the resource and disclose whether the access was on mutually agreed terms. The TRIPS/CBD linkage is, therefore, important for developing countries because it seeks to address biopiracy.

33. India is also of the view that a briefing by the CBD Secretariat on the latest developments in the implementation of the Nagoya Protocol would be very useful for a large majority of the Membership of this Council. India also supports updating of three factual briefs by the Secretariat on these issues.

#### **5.2 South Africa**

34. South Africa is a Contracting Party to the Convention on Biological Diversity (CBD) and ratified the Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilization in 2013 which came into force October 2014.

35. The Access Benefit Sharing (ABS) legal framework for South Africa is contained in Chapter 6 of National Environmental Management: Biodiversity Act No 3, 2003. This Act regulates, *inter alia*, bioprospecting involving indigenous genetic and biological resources; the exportation of indigenous genetic and biological resources for purposes of bioprospecting or any other research purpose; and provides for a fair and equitable sharing by stakeholders in benefits arising from bioprospecting.

36. South Africa also requires disclosure of the use of traditional knowledge or biological resources in patent applications. Sections 30 (3A) of the Patents Act No. 37 of 1952 as amended by Act No. 20 of 2005 require that:

- "(3A) Every applicant who lodges an application for a patent accompanied by a complete specification shall, before acceptance of the application, lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use."

37. These amendments to the Patents Act came into force on 14 December 2007 by proclamation and with the publication of Regulations for the Patents Amendment Act. As a result, every applicant for a patent (with the exception of provisional patent applications) filed in South Africa on or after

14 December 2007 is required to lodge a declaration or statement in respect of traditional knowledge or use of indigenous biological resources, irrespective of the nature of the invention sought to be protected.

38. The South African National Recordal System (NRS) is a defensive anti-appropriation strategy which was launched on 24 March 2013 by the Department of Science and Technology (DST) in response to the Indigenous Knowledge System (IKS) Policy adopted by the South African government in 2004. The Recordal System, which is loosely modelled upon India's Traditional Knowledge Digital Library (TKDL), seeks to capture, preserve, manage and disseminate traditional knowledge in digital format, while simultaneously enabling processes to derive benefit from the traditional knowledge. The NRS, which has been developed in phases, currently focuses on traditional knowledge of both African traditional medicine and indigenous foods, while the protection of traditional knowledge relating to arts, crafts and farming practices will be developed at a later stage.

39. Despite the already extensive legal regime that applies in South Africa, we still experience significant instances of biopiracy and misappropriation. National regimes are therefore necessary, but insufficient steps to protect traditional knowledge or the use of indigenous biological resources. A multilateral system within the context of the TRIPS Agreement that regulates disclosure and access remains the best guarantee against misappropriation of genetic resources and traditional knowledge.

40. In respect of procedural issues, South Africa once again calls on the Secretariat to update the three factual notes contained in documents IP/C/W/368/Rev.1, IP/C/W/369/Rev.1 and IP/C/W/370/Rev.1. We further reiterate our support for a briefing by the CBD Secretariat on the Nagoya Protocol and subsequent developments.

### **5.3 Ecuador**

41. Ecuador would like to confirm the views it expressed at previous meetings regarding these issues and the need to review Article 27.3(b) of the TRIPS Agreement.

42. We reiterate our position that patents for all life forms and parts thereof should be prohibited, as life forms and parts thereof cannot be considered tradeable goods subject to possible inventions. Viewing them as such would endanger or negatively affect them.

43. It is important that the TRIPS Agreement and the Convention on Biological Diversity are mutually supportive in their objectives, in particular as regards access to genetic resources and the fair and equitable sharing of benefits arising from their utilization, and prior informed consent. Regarding the utilization of genetic resources and associated traditional knowledge, it is vital to disclose both the origin and source in the country that provided the genetic resources and associated traditional knowledge. In this context, it is important to have multilateral legal instruments that can improve the utilization and protection of genetic resources, traditional knowledge and traditional cultural expressions, since the absence of clear regulations on intellectual property rights over living organisms has allowed for the proliferation of practices such as biopiracy and bioprospecting.

44. Lastly, we would like to insist on our request that the Secretariat update the factual notes on the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the review of the provisions of Article 27.3(b) of the TRIPS Agreement, and the protection of traditional knowledge, which were last updated in 2006. As you already know, the aim of this request is to ensure that Members have updated elements of analysis that can enrich the discussions on these issues, without prejudice to each Member's individual position. We call on the delegation of the United States to show flexibility in its position so as to enable the Secretariat to update the aforementioned factual notes and, in this way, advance the work of this Council.

### **5.4 China**

45. The relationship between the TRIPS Agreement and the CBD is an important issue in this Council. Over the years, Members have conducted a lot of useful discussion on this issue. China attaches great importance to the issue of TRIPS-CBD and hopes that Members could constructively involve in this discussion. As a large country for genetic resources, China attaches great importance to these issues. China joined the CBD as early as 1983 and joined the Nagoya Protocol in 2016. At

the same time, China makes efforts to improve domestic legislation. The Patent Law stipulates the disclosure of genetic resources, requiring that the direct and original resource should be illustrated when inventions and creations are based on genetic resources.

46. Regarding the substantial issues, China notes that the majority of Members support to amend the TRIPS Agreement to ensure the mutual supportiveness between the TRIPS Agreement, the CBD and the Nagoya Protocol. As to the issue of disclosure, China has provided detailed suggestions on negotiation modes, improving the transparency on genetic resources utilization, preventing misappropriation of genetic resources and traditional knowledge, and preventing the grant of erroneous patents in documents TN/C/W/52 and TN/C/W/59 co-sponsored by China and other Members. China also believes that setting up a reasonable system for prior informed consent and benefit sharing could make better protection of genetic resources.

47. As regard to the procedure, China supports to invite the CBD Secretariat to brief on the Nagoya Protocol and hopes that the Secretariat could revise three factual notes (IP/C/W/368/Rev.1, IP/C/W/369/Rev.1 and IP/C/W/370/Rev.1) which can contribute greatly to our discussion. China believes that discussion and negotiation in WIPO IGC could not hinder Members from finding solutions in the WTO as the Ministers have given the Council the mandate to examine the relationship between the TRIPS Agreement and the CBD. The WTO and WIPO are different platforms for discussion and research. Discussions in both platforms are conducive to solution-finding.

### **5.5 Bolivia, Plurinational State of**

48. The Plurinational State of Bolivia wishes to reiterate the relevance of document IP/C/W/545 of 26 February 2010, in which it submitted a contribution to this Council. We would like to emphasize the importance of keeping this item under discussion and on this Council's agenda. We also support the idea to update the three factual notes. The review of Article 27.3(b) is an issue within the mandate of the Doha Development Agenda under Paragraph 19 of the 2001 Doha Ministerial Declaration. Article 27.3(b) must be clarified in order to prohibit the patenting of all life forms and to protect all the rights of farmers, genetic resources, traditional knowledge and traditional practices in developing countries.

### **5.6 United States of America**

49. Regarding genetic resources, traditional knowledge and folklore, we continue to believe that WIPO serves as the best forum to address these issues. The WIPO IGC is looking at addressing unresolved issues and working on a common understanding of core issues, using an evidence-based approach and examples of national experiences. The United States will continue to engage in technical discussions at WIPO IGC and looks forward to hearing more from the *demandeurs* regarding data supporting their positions on this issue.

50. With respect to the various requests made in the meeting, the United States is not in a position to support them, but remains open to discussions, including bilaterally with delegations in between and at the margins of the TRIPS Council meetings.

### **5.7 Japan**

51. We have discussed this agenda item at length during a series of meetings of the TRIPS Council. This delegation, therefore, believes that our position is well-recognized among Members, so we would like to make our intervention brief by highlighting some major points.

52. The delegation of Japan would like to reiterate our position that the Convention on Biological Diversity is by nature not relevant to the intellectual property system. Therefore, we need to seek appropriate ways to deal with misappropriation of genetic resources. This means that we should bear in mind that any measures taken must not adversely affect the existing intellectual property system or hinder the creation of innovations utilizing genetic resources and associated traditional knowledge. Japan is firmly convinced that to include the disclosure requirement in the IP system would discourage industries from conducting research and development activities on biological materials. This is the very consequence of the disclosure requirement that Japan has been concerned about. The same holds true for not only developed countries but also emerging and developing countries. Therefore, Japan believes that the disclosure requirement is not an adequate means for

dealing with the misappropriation of genetic resources. In line with the above-mentioned position, we firmly believe that the protection of genetic resources, traditional knowledge and folklore, and traditional cultural expressions should be designed in a manner that supports creativity and innovation.

53. In addition, this delegation believes that the WIPO IGC is the most appropriate forum for holding technical discussion on genetic resources, traditional knowledge and folklore from IP aspects, and the 39<sup>th</sup> and 40<sup>th</sup> sessions of the WIPO IGC are planned to be held in the first half of this year. This delegation has been actively contributing to the discussion at the IGC meetings, making various proposals, and remain willing to contribute to evidence-based discussion on these issues in a constructive and effective manner.

#### **5.8 Brazil**

54. Brazil has a well-known position on the importance of promoting the neutral supportiveness between the TRIPS Agreement and the Convention on Biological Diversity (CBD), which is contained in document TN/C/W/59. Enhancing the transparency and utilization of genetic resources and associated traditional knowledge through the introduction of a mandatory requirement of the disclosure of the origin in patent applications will reinforce the view that IP rules can work for the benefit of all countries and stakeholders.

55. Biopiracy and misappropriation of traditional knowledge and traditional cultural expressions continue to occur. An amendment to the TRIPS Agreement would ensure cooperation between countries, reduce uncertainty for stakeholders and curb illegal activities related to this matter.

#### **5.9 Canada**

56. Canada continues to firmly believe that the TRIPS Agreement and the Convention on Biological Diversity are complementary, and that there is therefore no need to amend the TRIPS Agreement in this regard.

57. Canada welcomes the ongoing work of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). Canada views the IGC as the best and most appropriate forum for discussion on these complex issues. It is an important venue to bring together expert views to discuss IP related issues in order to identify evidence-based, balanced, appropriate and mutually-beneficial approaches. Canada has been, and continues to be, an active and committed participant to this important work, and welcomes the concrete discussions and exchanges of national experiences at the IGC, which are so important to identify the issues at hand. In this regard, Canada looks forward to the upcoming 39<sup>th</sup> session of the IGC in March 2019.

58. With respect to procedural matters at the TRIPS Council, as Canada has previously noted, and without prejudice to our position on substantive matters, Canada can support from a procedural standpoint a briefing from the CBD Secretariat to the TRIPS Council, should there be sufficient interest from other Members on the matter. Canada could also support the compilation of the three factual notes on the TRIPS Agreement and the CBD, review of Article 27.3(b), and protection of traditional knowledge (documents IP/C/W/368/Rev.1, IP/C/W/369/Rev.1, and IP/C/W/370/Rev.1) by the WTO Secretariat. Canada remains of the understanding that this would remain an information collating exercise, and in both cases, this is without prejudice to national positions on these issues.

#### **5.10 Switzerland**

59. The relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD), including the question of a disclosure requirement for genetic resources, has been on the agenda of the TRIPS Council and the WTO as outstanding implementation issues for many years. Switzerland recognizes that these are important concerns for many biodiversity rich countries. Switzerland, being a Party to both the CBD and the TRIPS Agreement, remain open to continue exploring ways to further enhance the mutual supportiveness of both international agreements.

60. Transparency is inherent to the patent system. Transparency is also of key importance in the utilization of genetic resources and associated traditional knowledge. If an invention is directly based on genetic resources or traditional knowledge, transparency could be further enhanced by disclosing

information on the source of the respective genetic resources or traditional knowledge. Such a disclosure requirement must be adequate, practical, non-burdensome and non-prejudicial to an expeditious and effective patent application, examination and granting procedure. By working out a solution along these criteria for the specific context of the TRIPS regulatory framework, the WTO will not only enhance transparency but also legal certainty at the international level.

61. Switzerland is of the view that such a solution will serve the advancement and promotion of the patent system, in particular in relation to inventions in the field of biotechnology. These are some reasons why Switzerland is one of the coalitions of 109 Members that tabled document TN/C/W/52. It contains modalities proposals for such a requirement to disclose the source of genetic resources and traditional knowledge in patent applications as well as for enhanced protection of geographical indications, thus combining working proposals on these two outstanding implementation issues.

62. Finally, Switzerland supports the request to the Secretariat to update its factual compilation notes on the discussions under these three agenda items and to invite the CBD Secretariat to brief the TRIPS Council on the Nagoya Protocol.

### **5.11 Australia**

63. Australia believes that the WIPO IGC is best placed, with appropriate technical expertise, to consider the important and complex issues relating to intellectual property and genetic resources and associated traditional knowledge, and cultural expressions. Australia hopes WIPO Members will adopt a spirit of compromise when the issue of genetic resources is next considered in 2019. Australia will continue to be an active and constructive participant in the IGC process.

64. Australia believes the TRIPS Agreement and the Convention on Biological Diversity are fully consistent, and that the TRIPS Agreement therefore does not need to be amended. Australia fully implements its obligations under both agreements, which we view as mutually supportive.

65. In relation to procedural matters, Australia is open to a briefing by the CBD Secretariat on the Nagoya Protocol, and can be flexible in relation to the Secretariat updating the three factual notes.

### **5.12 Indonesia**

66. Indonesia's position is well-known, and we are in the process of incorporating the CBD provisions in our IP system. We believe that the TRIPS-CBD issue is important for most Members of the WTO and for this reason we would like to emphasize the following: we need to ensure the consistency and mutual supportiveness between the TRIPS Agreement and the Convention on Biological Diversity. We need to take necessary measures to ensure fair and equitable sharing of benefit arising from the utilization of genetic resources, traditional knowledge and folklore through the establishment of a disclosure requirement for patent applications. We also need assume substantive discussion in this Council as complementary to the discussion in other fora, such as WIPO with the view of achieving a fair and balanced trading system with regard to intellectual property. Indonesia also supports the suggestion that the CBD Secretariat be given an opportunity to brief the Council on any development related to the CBD and also urges the WTO Secretariat to update the factual notes.

### **5.13 Chile**

67. Regarding this agenda item, our delegation would like to reiterate the importance of the flexibilities contained in the TRIPS Agreement. In this respect, we understand that the flexibilities provided for in Article 27 of the Agreement enable each Member to take into account its own ethical and public health standards, among other criteria, when developing its intellectual property system. For Chile, it is important that such flexibility can be preserved insofar as it allows each Member to rethink and modify its intellectual property model in the light of its own social, cultural and economic changes.

68. In Chile's view, intellectual property systems are not an end in themselves, but are tools for promoting innovation and development while also facilitating access to information and health. This vision is reflected in Law No. 19.039 on industrial property, which excludes the patentability of plants and animals.

69. Chile, like other delegations, considers that the TRIPS Agreement and the CBD are complementary instruments. We therefore believe that there is no need to make any amendments to the TRIPS Agreement to ensure that they are consistent with each other. We wish to highlight the important work being done at the WIPO on genetic resources, traditional knowledge and traditional cultural expressions, and reaffirm Chile's commitment to continue working and facilitating discussion in that forum.

70. Finally, we would like to express our support for the proposal that the CBD Secretariat provide a briefing to this Council. We believe that a factual description could shed light on this topic for Members and promote dialogue.

## **6 NON-VIOLATION AND SITUATION COMPLAINTS**

### **6.1 South Africa**

71. South Africa is not a proponent for the application of draft modalities in respect of Non-Violation and Situation Complaints (NVSCs). However, we remain open to discuss any ideas that delegations may have in this regard. At the last TRIPS Council meeting we identified a few useful elements that can inform any debate that Members may wish to have on the subject of non-violation and situation complaints as they pertain to the TRIPS Agreement.

### **6.2 India**

72. India's position on the issue of non-violation and situation complaints (NVSCs) under the TRIPS Agreement remains unchanged. Serious concerns remain on the debilitating impact that NVSCs in TRIPS can have on the regulatory policy space of Members, on TRIPS flexibilities as well as increasing the complexity in interpreting the TRIPS provisions.

73. The absence of NVSCs in the TRIPS context does not in any manner threaten or dilute the enforceability of TRIPS-related rights and obligations. Introducing NVSCs into the TRIPS Agreement is unnecessary and inconsistent with the interests of WTO Members. As such, any benefits arising from the Agreement can be adequately protected by applying the text of the Agreement in accordance with accepted principles of international law, without any need for introducing the legally uncertain notion of NVSCs.

74. India looks forward to working with like-minded Members in making NVSCs inapplicable to TRIPS.

### **6.3 United States of America**

75. The United States' position on this issue remains unchanged. We reiterate our support for allowing the current moratorium to expire so that Members may bring NVNI complaints in the future, as appropriate.

76. In the previous TRIPS Council meeting, some Members raised concerns over the application of NVNI complaints to the TRIPS Agreement. We believe that while valid questions have arisen, they are fully and adequately answered by the text of the TRIPS Agreement itself and further clarified through GATT and WTO adjudication, as we have enumerated in our communication to the TRIPS Council, which was circulated to Members as IP/C/W/599.

77. The United States has provided detailed and extensive analysis in each of our statements under this item over the past several years. We have explained the legal basis for such claims in the GATT and TRIPS Agreement texts, the panel and Appellate Body jurisprudence involving NVNI disputes, the extensive safeguards that exist to protect Members rights and obligations under the TRIPS Agreement, and concrete descriptions regarding how such disputes would work in practice.

78. As we have detailed in past interventions, NVNI claims have a long lineage in the WTO and in international trade law generally. The applicability of such claims to the WTO Agreements is the rule; their non-application is the exception. The TRIPS Agreement moratorium is the exception.

79. We continue to believe that WTO Members are being deprived of an important tool to enforce their rights under the TRIPS Agreement, which is why we support the expiration of the current moratorium so that complaints of this type may be applicable to the TRIPS Agreement.

80. While we remain of the view that the text of the WTO Agreements and dispute settlement rulings provide Members with sufficient guidance on the application of NVNI disputes to the TRIPS Agreement, the United States remains open to considering specific proposal from Members wishing to further examine the scope and modalities for complaints of these types.

#### **6.4 Brazil**

81. Brazil's position on this matter is well-known and remains unchanged. Brazil reiterates its understanding that NVSCs should not be applied to the TRIPS Agreement.

#### **6.5 Ecuador**

82. Under this item, Ecuador wishes to reiterate its view that NVSCs do not apply to the TRIPS Agreement as this Agreement does not seek to protect market access, as there is no exchange of tariff concessions.

83. We expressed this position in document IP/C/W/385/Rev.1, which we co-sponsored. The document refers to the scope and modalities for complaints of the types provided for under Article XXIII:1(b) and (c) of the GATT 1994, which are not applicable in this area of dispute settlement.

#### **6.6 Russian Federation**

84. The Russian Delegation would like to reiterate our position on the issue of non-violation complaints. We consider that non-violation and situation complaints shall not be applicable to disputes under the TRIPS Agreement. Such disputes are unnecessary and inconsistent with the interest of the WTO Membership since it is going to disrupt the balance of rights and obligations under the Agreement. Any benefits arising from the Agreement can be adequately protected by applying the text of the Agreement in accordance with established principles of international law, without recourse to legally imprecise notion of non-violation and situation complaints.

#### **6.7 Switzerland**

85. For the details of Switzerland's position regarding the application of NVSCs under the TRIPS Agreement and the expiration of the moratorium, I refer to the interventions of my delegation in past Council meetings. I therefore limit myself to reiterating that we stand ready to discuss any proposals of Members, should they consider specific modalities for such complaints necessary in the TRIPS context beyond those already contained in the DSU and those that can be derived from WTO jurisdiction.

#### **6.8 Argentina**

86. Argentina's position on this matter is well-known and remains unchanged. We believe that complaints of this type are not applicable to the TRIPS Agreement, as explained in document IP/C/W/385/Rev.1, which Argentina co-sponsored together with a large number of other Members.

#### **6.9 Chinese Taipei**

87. My delegation recognizes the concerns of Members on the applicability of NVSCs to the TRIPS Agreement. We are looking forward to having substantive discussion with Members in this Council on this issue.

#### **6.10 Canada**

88. Our position on this issue is well-known and remains unchanged. Canada continues to have concerns regarding the applicability of the NVNI remedy to the TRIPS Agreement.

89. Recognizing that the current moratorium exists based on consensus, Canada wishes to express its continued interest in participating in any consultations that take place on this issue amongst other interested Members.

### **6.11 China**

90. China reaffirms the position that non-violation and situation complaints are not applicable under the TRIPS Agreement, which has been elaborated in document IP/C/W/385/Rev.1 proposed by 16 Members including China. We also welcome the discussion on this issue in accordance with decision and mandate given by Buenos Aires Ministerial Conference.

## **7 REVIEW OF THE IMPLEMENTATION OF THE TRIPS AGREEMENT UNDER ARTICLE 71.1**

91. No statements were made under this agenda item.

## **8 REVIEW OF THE APPLICATION OF THE PROVISIONS OF THE SECTION ON GEOGRAPHICAL INDICATIONS UNDER ARTICLE 24.2**

### **8.1 Montenegro**

92. The protection of geographical indications in Montenegro is governed by the Law on Indications of Geographical Origin, the Law on Quality Schemes for Agricultural and Food Products, the Law on Wine and the Law on Spirit Drinks.

93. The Law on Indications of Geographical Origin does not apply to products and services where the acquisition, legal protection and the exercise of rights in respect of the use of the indication of geographical origin is regulated by a specific regulation.

94. Protection of geographical indications is conditioned on registration. Geographical indications for agriculture and food products, spirit drinks and wines are registered in the Ministry of Agriculture and Rural Development, while GIs for all other products are registered in the Intellectual Property Office of Montenegro – Ministry of Economy.

95. In accordance with the aforementioned legislation, foreign natural or legal persons, or foreign associations may apply for the registration of a geographical indication, if the geographical indication was recognized in the country of origin, when it stems from the international agreements.

96. Recognition of a geographical indication does not need to be renewed or reaffirmed, also a geographical indication does not need to be used in order to maintain rights.

97. The decision on registration of the designation of origin, or geographical indication shall be cancelled in cases where no product protected with the designation of origin or geographical indication has been marketed for at least seven years.

98. "Njeguški pršut", "Pljevaljski sir", "Crnogorska goveđa pršuta", "Crnogorska stelja" and "Crnogorski pršut" are some of the Agricultural and Food Products labelled with a protected geographical origin, and I invite you if you have opportunity to try some of them. Unfortunately, I could not find them on the market in Geneva.

### **8.2 Norway**

99. Norway has updated its review of the application of the provisions of the section on geographical indications under TRIPS Article 24.2, the so-called checklist of questions. Our answers to the checklist are contained in IP/C/W/117/Add.7/Rev.1.

100. The updated review takes account of the established sui generis-system for registration of geographical indications, designations of origin and traditional specialities for foodstuffs. The sui generis system offers protection at the same level as provided for wines and spirits under Article 23 of the TRIPS Agreement.

101. We invite Members to have a look at the mentioned document for detailed answers to the questions. We also encourage other WTO Members to provide their answers or updated answers to the checklist.

### **8.3 Switzerland**

102. Switzerland would like to thank Montenegro for submitting its answers to the checklist of questions and Norway for up-dating its initial set of responses. I would also like to thank both delegates for giving a brief account on the responses and the up-date submitted.

103. Switzerland encourages other Members to follow suit. Comprehensive and up-to-date information from Members is the basis needed for the Council to usefully undertake the review stipulated in Article 24.2 of the TRIPS Agreement.

104. In this context, Switzerland would like to inform the Council that in the English translation of Switzerland's up-dated answers to the checklist, a number of corrections were made to make it comply with the French original as submitted to the WTO at the end of 2017.

105. Switzerland thanks the WTO Secretariat for carrying out these corrections and for making the amended English translation available on the WTO database.

## **9 FOLLOW-UP TO THE SIXTEENTH ANNUAL REVIEW UNDER PARAGRAPH 2 OF THE DECISION ON THE IMPLEMENTATION OF ARTICLE 66.2 OF THE TRIPS AGREEMENT**

### **9.1 Chad, on behalf of the LDC Group**

106. On behalf of the WTO LDC Group, I would like to take this opportunity to express our sincere thanks to the Chair for his leadership over the course of the Workshop on the Implementation of Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) held on 11 and 12 February at the WTO.

107. The LDC Group would also like to thank and congratulate all the workshop participants for their enthusiastic and constructive involvement throughout the event. The LDC Group welcomes the opportunity provided for representatives from the capitals to give detailed presentations on items related to the priority areas in technological development under consideration. This was also an opportunity for individual LDCs to share their experiences with respect to priority projects – particularly those set out in the reports on Article 66.2 of the TRIPS Agreement.

108. We would also like to express our gratitude to our developed country Members (the United States of America, Japan, Australia, the European Union, Canada, Norway, Switzerland and New Zealand) and all the other Members that took an active part in the workshop. The developed country Members presented a comprehensive summary of their reports and responded to some of our questions regarding observance of Article 66.2 of the TRIPS Agreement.

109. The LDC Group also warmly welcomes the WTO Secretariat's commitment to supporting the efforts of LDCs to promote their economic and trade priorities through its organization of this workshop under a new format, which includes the increased involvement of multilateral and regional partner organizations.

110. The preliminary assessment that we have conducted shows that some of the programmes mentioned by the developed country Members seem to improve the level of information and lead to technology transfer and incentives. However, it also appears that other programmes mentioned in the reports do not relate to Article 66.2 and are not consistent with it, even though what is required of developed country Members in this context is to specifically address and report on technology transfer and incentives under the article in question.

111. There were two sides to the workshop held over the last two days. First, LDC participants had the opportunity to discuss their priority areas with respect to technological development and provide their views on the projects under Article 66.2 included in the reports of certain developed country Members. Second, developed country Members were able to present their 2018 reports specifically on the implementation of Article 66.2 of the TRIPS Agreement.

112. In the follow up on this issue, we would encourage our partners to be more explicit and focused on technology transfer under Article 66.2 of the TRIPS Agreement. One thing is certain, and that is that this year's workshop has allowed for enhanced dialogue between LDCs and their developed country Members, which is very positive and likely to foster a more effective implementation of Article 66.2. LDCs need to develop a sound and viable technological base, not only under Article 66.2 but also in accordance with Article 66.1, taking into account both the development of a technological base and the UN Sustainable Development Goals.

113. LDCs have a genuine need for incentives put in place by developed country Members to promote and encourage technology transfer to LDCs. We need to understand how the programmes developed actually contribute to technology transfer and incentives for transfer. We need Members to work actively alongside us in this area.

114. As we end this workshop on technology transfer to LDCs under Article 66.2, the LDC Group supports the conclusions that have been drawn, particularly with a view to improving communication on the issue between LDCs and developed country Members. Access to relevant information will allow us to better gauge the implementation of and follow up on Article 66.2.

115. It would therefore be useful to designate focal points among the LDCs to monitor technology transfer and ensure appropriate follow up. It seems to us that this is an important suggestion that should be made operational.

116. Likewise, designating focal points among developed country Members to engage in the same follow up would be particularly relevant and help meet the expectations of LDCs.

117. The LDC Group appreciates these direct and productive exchanges with developed country Members and thanks them for their flexibility in taking into account the LDCs' suggestions with respect to the priority projects raised. We fully support maintaining the new format for discussions.

118. Technology transfer to LDCs is a key and decisive factor in our countries' economic growth. It is therefore important to emphasize that applying Article 66.2 and improving the use of the transparency mechanism on incentives for transfer of technology will undoubtedly contribute to improving relations between LDCs and our developed country Members in the short, medium and long term.

119. On behalf of the LDC Group, we remain committed to a productive discussion on the implementation of Article 66.2 of the TRIPS Agreement and the continued involvement of our partners.

120. We should continue to pursue these joint efforts to support LDCs in building institutional and human capacity so that they are able to integrate and develop technology that is appropriate to their economic growth.

## **9.2 Central African Republic**

121. The Central African Republic supports the statement made by the LDC coordinator. It wishes to thank the WTO Secretariat for organizing the Workshop on the Implementation of Article 66.2 of the TRIPS Agreement. The Workshop is important not only for enabling a clear understanding of this Article but also for highlighting the willingness of developed country Members to support our countries in implementing technology transfer.

122. To this end, we urge developed countries to facilitate these transfers of technology to our countries for the purpose of improving the economic situation and thereby enabling active participation in the multilateral trading system. In addition, developed Members can favour endogenous technologies that meet the needs of LDCs.

123. Lastly, the delegation of the Central African Republic would like to thank countries which are open to discussions on this matter.

### 9.3 Senegal

124. Senegal would like to join the LDC coordinator in thanking the WTO Secretariat for organizing the Workshop on the Implementation of Article 66.2 of the TRIPS Agreement.

125. This workshop, which brought together LDC delegates (both capital and Geneva-based) and delegates from developed country Members that had submitted reports, provided a good forum for discussion on the relevance and effectiveness of technology transfer under Article 66.2 of the TRIPS Agreement. It enabled LDCs to indicate the priority areas for technology transfer, to report on the results of the implementation of technology transfer projects and to make recommendations on the steps to take to improve the evaluation process.

126. The recommendations made include the following:

- a. The setting up of focal points at LDC and developed country Members level in order to coordinate and report on the incentives provided by developed country Members to enterprises and institutions in their territories for the purpose of promoting technology transfer to LDCs, and the results achieved in LDCs.
- b. Ensuring the compatibility of technology transfer projects with the needs and priorities expressed by LDCs.

127. Improving reports so as to make them more specific and consistent with the letter and spirit of Article 66.2.

128. We hope that all the recommendations emanating from the workshop will help to improve the review under paragraph 2 of the decision on implementation of Article 66.2 of the TRIPS Agreement. In this respect, Senegal encourages the Secretariat to pursue this initiative further in the context of the Council's future work.

129. Lastly, Senegal wishes to thank the developed country Members for their reports.

### 9.4 Myanmar

130. It is a pleasure to have the opportunity to speak this morning at this important meeting. First of all, on behalf of Myanmar, I would like to express special thanks to the WTO for its assistance to hold the Workshop on the Implementation of Article 66.2 of the TRIP Agreement, and also express thanks to the LDC participants for their presentations despite their busy schedules and finally thanks to all Members which presented at the Workshop and in this Council meeting.

131. The Government of Myanmar is exerting its best efforts for all-round development of the country by undertaking a series of political and economic reforms to achieve the vision of becoming a modern, democratic and developed country Member by 2030. Although Myanmar is a least developed country and lacks enough capacity building to fulfil its obligation as a Member of WTO, it is making every best effort.

132. Myanmar is also continuously working in the area of legislation on trade-related laws and policies such as FDI law, company law, IP laws, competitive policy, etc. Concerning IP laws, the Industrial Design Law and Trademark law have already been approved by the Union Parliament and were signed by the President in January 2019. The remaining two IP laws, on patent and copyright, will also come out soon.

133. In such a situation, it is also extremely grateful to the developed country Members for assisting technical assistance and technology transfer according to the Article 66.2, both of which are very much beneficial for Myanmar people. Technical assistance and capacity building are essential for Myanmar to be able to overcome the big challenges it faces, especially regarding trade and technological development.

134. Article 66.2 of the TRIP Agreement is very supportive for the development of LDCs like Myanmar. Encouraging technology transfer in one country will provide technology promotion there. This will, in turn, create an environment for innovation, and will benefit not only the host country, but also the development partner. Therefore, we should consider this Article to be applied

continuously for mutual interest. In Myanmar, we have already setup our Sustainable Developing Goals, Economic Policy and Development Assistance Policy, etc. for carrying out country development. In this connection, we would like to refer our Myanmar Development Assistance Policy, 2018 in building an effective cooperation between us.

135. In conclusion, we would like to inform you that we are ready to constructively engage and to closely work together with the Members of WTO to enabling ourselves to build a sound and viable technological base in order to meaningfully improve Article 66.2 implementation.

### **9.5 Bangladesh**

136. The delegation of Bangladesh sincerely thanks the Secretariat for organizing the Workshop on Implementation of TRIPS Article 66.2. It was a great opportunity to hear both the development partners and the targeted LDCs, particularly from their capital-based delegates. However, we should be honest to admit that not all assistance programmes are technology transfer as stated in TRIPS Article 66.2 that aims to ensure sound and viable technological base in the LDCs. But we must acknowledge that many technical assistance programmes, a large portion of which falls under TRIPS Article 67, by the development partners are helping the LDCs in capacity enhancement in different areas. Many projects and programmes cited in the workshop by the LDC delegates are virtually the examples of technical assistance programmes.

137. The delegation of Bangladesh supports the proposals by the delegation of Chad and Central African Republic that we need regular dialogues on the TRIPS Article 66.2 implementation. We encourage the Secretariat to arrange such workshops on regular intervals involving more LDC Members. We also welcome the proposal of appointing a focal point on the implementation status of TRIPS Article 66.2.

### **9.6 Vanuatu**

138. Vanuatu supports the statements made by Chad on behalf of the LDC Group and the previous LDC Members.

139. In addition, Vanuatu thanks the WTO Secretariat for organizing this workshop and for allowing our LDC capitals-based officials to participate and share experiences.

140. Secondly, Vanuatu fully support the establishment of the focal points in both LDC and developed country Members to facilitate coordination and information sharing.

### **9.7 Japan**

141. Japan thanks the Secretariat for organizing the Workshop on the Implementation of Article 66.2 of the TRIPS Agreement, which was held back-to-back to this Council. The Workshop worked to advance cooperative activities and enhance mutual understanding between developed country Members and LDC Members.

142. Japan will continue to make its utmost efforts to improve the business environment and make it even more conducive to transfer technology. We look forward to working further with LDC Members in this context.

### **9.8 Australia**

143. We warmly welcomed the opportunity to discuss Australia's technology transfer activities with LDC Members over the past two days at the Workshop on the Implementation of Article 66.2 of the TRIPS Agreement.

144. We would like to register our appreciation for the hard work of the Secretariat in organising this important event. We also thank all participants for this productive exchange.

145. At the workshop we presented some specific examples of Australia's compliance with its Article 66.2 obligations, including the Cambodia Agricultural Value Chain Program (CAVAC), which

has given farmers in four Cambodian provinces access to cutting edge agricultural technology and improved seed varieties, helping them to improve yields and make their rice more competitive.

146. We paid close attention to the questions and feedback provided by LDC Members on our Article 66.2 reporting, and welcomed the opportunity presented by the Workshop to engage on these issues.

### **9.9 Switzerland**

147. Switzerland was pleased to participate in this year's Workshop on the Implementation of Article 66.2 of the TRIPS Agreement and to learn about LDCs priority sectors for technology transfer. We thank the Secretariat for its organization and for leading the workshop in an efficient manner.

148. It was particularly helpful to see some concrete examples of technology transfer that have effectively worked in practice. This serves developed country Members as an orientation when developing incentives measures and planning tailor made projects together with LDC partners.

149. We believe that the presentations of the LDCs during the workshop should not only contain examples of past or current projects. We encourage LDCs to also present planned project outlines as concretely as possible. The presentation of Myanmar was very helpful in this regard to understand what is concretely needed. We encourage other LDCs to present similar concrete project outlines in the future.

150. Switzerland remains committed to engaging in the Council's discussion on Article 66.2 and to further developing its incentive measures to enterprises and institutions in Switzerland for the purpose of promoting and encouraging technology transfer to LDCs.

### **9.10 United States of America**

151. United States also thank the Secretariat for its efforts in organizing the Workshop. We also found it to be an excellent programme that, in particular, benefited from the participation of capital-based officials from LDCs.

152. The United States appreciated the opportunity to present and share details on our most recent Article 66.2 submission IP/C/W/646.

153. At the workshop we gained insight into the perspective and needs of LDCs and hope that the LDC Members also left the workshop with a better understanding of our extensive programmes and activities.

154. We took note of the idea shared during this week's workshop of the designation of focal points on 66.2 reports for both LDC and developed country Members.

155. We understand that LDC focal points could play an important role in disseminating information or reports about technology transfer programmes and their effectiveness to broader audiences, so technology transfer projects could be better leveraged in the country.

156. However, with respect to the United States, the nature of our programmes and technical assistance do not immediately seem to lend themselves to such a structure under the WTO.

157. It is quite an undertaking each year to take stock of the programmes we report to the TRIPS Council. As you can see from our recent reports, there is not one coordinating body that undertakes all of these programs. We therefore view it best to continue to implement these programmes and these reports as we have.

158. Of course, we are always willing to meet with interested Members to discuss ways to ensure that our programmes and reports are as helpful as possible.

### 9.11 Norway

159. Norway thanks the Secretariat for its hard work in putting together the very comprehensive Workshop on the Implementation of Article 66.2 of the TRIPS Agreement in which we attended these past two days. The Workshop was an excellent opportunity for exchange between LDC Members and developed country Members.

160. Norway already gave a brief presentation of our report in the meeting of the TRIPS Council in November. In the interest of time, we will therefore refrain from doing so again in this meeting.

161. The TRIPS Article 66.2 report from Norway is contained in document IP/C/W/646/Add.5.

162. Norway presented its report at the Workshop on the Implementation of Article 66.2 of the TRIPS Agreement and had a useful discussion afterwards. We would like to thank the LCDs for their interest in our report and the questions and comments we received. We aim to respond to these in writing as soon as possible.

### 9.12 New Zealand

163. New Zealand also wants to thank the Secretariat for organizing what was a very effective workshop. Was a pleasure to engage in a dialogue on which assist us all to an understanding on what Article 66.2 provides. The basis for my remarks today is report which New Zealand submitted on its Implementation of Article 66.2 covering the period from June 2017 to June 2018. We have lodged this with the Secretariat and you'll find this at document reference IP/C/W/646/Add.6.

### 9.13 European Union

164. The European Union and its Members take their commitments and obligations under Article 66.2 of the TRIPS Agreement very seriously and try to deliver technology transfer programmes to LDCs in a way that reacts to natural, social, health, climate and economic changes. The programmes are specifically tailored to the needs of least developed countries (LDCs) and their regional organizations. The programmes listed in the EU report are provided by the European Commission or other European institutions or the EU Members. The main incentive for the EU companies or organisations to voluntarily transfer technologies to LDCs is that they get funding from the European Commission or the EU Members for these activities. The high number of programmes shows that this incentive has proven to be effective.

165. We would like to thank the Secretariat and also in particular the LDC participants for the very detailed and useful Workshop. We saw a lot of common ground and always stand ready for any fruitful exchanges.

166. The EU had presented its report at the last meeting and actively participated in the Workshop held from 11 to 12 February. In the interest of time, we therefore refrain from presenting our long list of exemplary projects again.

### 9.14 Canada

167. Canada would like to thank the Secretariat for organizing the thematic discussions and panels and Members for sharing their important insights on the implementation of Article 66.2 of the TRIPS Agreement. Canada places great importance on the implementation of Article 66.2, and on the annual workshop as an opportunity to exchange national experiences and practices, particularly with a view to ensuring that our continued implementation of the TRIPS Article 66.2 commitment remains responsive to the needs and priorities of LDCs over time in enabling them to create a sound and viable technological base.

168. In our experience, the clear identification and articulation of priority needs by LDCs is particularly important in ensuring that the outputs of Canada's tech transfer incentives are tailored to these objectives. Ensuring that our LDC partners have an opportunity to provide feedback on specific projects, as well as on their needs and priorities over time, will help provide that the incentives provided under our Article 66.2 commitment continue to enable LDCs to address new and emerging development challenges in creating a sound and viable technological base. We similarly

benefit from hearing the experiences of other developed country Members, in sharing and identifying best practices and commonalities, with a view to better informing Members of how future incentives in the area of technology transfer might best respond to LDCs' evolving priorities and needs over time.

169. In turn, these discussions can inform developed country Members in refining and tailoring the range of incentives provided to enterprises and institutions, in order to continue to meet the development needs of LDCs going forward.

170. In this spirit, Canada would be pleased to discuss any aspect of its 2018 report which can be found in document IP/C/W/646/Add.4 with interested LDC Members and looks forward to further dialogue through the annual workshop and at TRIPS Council. We once again thank the Secretariat for convening the Workshop on the Implementation of Article 66.2 of the TRIPS Agreement, and all Members for their constructive engagement on these important issues.

### **9.15 Senegal**

171. Senegal would like to react to a few observations made by the European Union and the United States on the idea of having focal points at the developed and LDC level. We are fully aware that it is not easy to ensure coordination of the whole set of structures and projects carry out for the implementation of Article 66.2. This require even more efforts in regard of payments. Some delegations mentioned during the Workshop experiencing some difficulties verifying the whole set of projects that were listed in the reports. But we think that this is a good starting point and it would be useful in this context to have focal points so that we can centralize and also to be able to respond at the WTO level.

172. In the workshop, during the Q&A session, some delegations that presented reports were not always able to reply to the questions following the presentation of the reports. Perhaps information was not available or the entities responsible for implementation at country level would have to be addressed directly. For example, there is Japan and other entities that are relevant to those contexts. It is our view that having focal points could help us resolve these challenges. LDCs stand ready to establishes this and we think that will be easier for developed country Members who have greater means for coordination than the LDCs do. To ensure that this happen, we would happily discuss this in an agreed date with the concerned delegations. On this proposal, and to improve our efforts.

### **9.16 Vanuatu**

173. Vanuatu took note of the report submitted by developed country Members during the Workshop and is wondering whether it could be possible to include in the reports some inputs from the beneficiary's countries. The LDCs are benefitting in general terms but there is a lack of coordination between beneficiary's and developed supporting countries.

174. Vanuatu suggests that, in order to have a better coordination and see what benefits LDCs are actually receiving from developed countries, it would be wise to adopt a format where the inputs from the beneficiaries could help in terms of moving forward.

### **9.17 African Regional Intellectual Property Organization**

175. The African Regional Intellectual Property Organization (ARIPO) would like to associate itself with the statement made by the delegation of Chad on behalf of the LDCs.

176. This delegation raises the flag to appreciate Secretariat for organizing the Workshop on the Implementation of Article 66.2 of the TRIPS Agreement: Incentives for Technology Transfer that was held in the past two days.

177. This workshop allowed the LDCs to showcase their development priorities and technological needs that technology transfer could assist in achieving.

178. We especially appreciate the new format that seems to be adequate to promote the dialogue between developed country Members and LDCs on the issues of technology transfer, especially with regard to the implementation of TRIPS Article 66.2.

179. We will not delve into the very important conclusions and recommendations emanating from this meeting but as this delegation is in fully agreement and support of those outputs it is our desire to encourage both developed country Members and LDCs to implement them.

180. Finally, we would like to encourage Secretariat to hold this kind of events possibly in regular basis and including more LDCs and relevant regional organizations. This delegation also believes that in future it would also be useful if sufficient time is given to capital-based delegations to gather the necessary information in order to be able to provide more detailed information on current and future priorities and projects in which they would like to receive support.

## **10 TECHNICAL COOPERATION AND CAPACITY BUILDING**

### **10.1 Australia**

181. Australia takes an active role in promoting technical cooperation and capacity building in the intellectual property field as we have highlighted in our 2018 Article 67 Report.

182. Since our last meeting, the ongoing work of the WIPO-Australia Funds in Trust (FIT) programme has continued to support least developed and developing country Members with the development and implementation of IP systems and enhancement of their IP capabilities.

183. We are pleased to reiterate our commitment to technical cooperation and intellectual property capacity building activities.

## **11 INTELLECTUAL PROPERTY AND INNOVATION: SUMMARY OF THE 2018 THEME – THE SOCIETAL VALUE OF IP IN THE NEW ECONOMY, AND 2019 IP AND INNOVATION THEME: PUBLIC-PRIVATE COLLABORATIONS IN INNOVATION**

### **11.1 United States of America**

184. The United States is pleased to co-sponsor this agenda item and contribute to the discussion of "Public-Private Collaborations in Innovation - Research and Development (R&D)."

185. The United States would like to thank the co-sponsors for this item.

186. Before providing the United States' experience with public-private collaborations in innovation, I would like to take a step back and summarize what we discussed last year under the theme - "The Societal Value of IP in the New Economy".

187. First, under the sub-theme - "IP Intensive Industries and their Economic Impact on Society" - a number of WTO Members provided empirical data from reports and case studies showing how intellectual property rights (IPRs) contribute to employment, gross domestic product (GDP), licensing revenue and trade. The discussions covered a broad range of IP-intensive industries, wherein the contributing Members offered examples of government resources available to support the IP-intensive sector generally, and, more specifically, new and emerging businesses, including micro, small and medium-sized enterprises (MSMEs). Members also identified ongoing and future studies to help improve their respective innovation landscapes, export strategies and IP policies.

188. Second, under the sub-theme - "IP and Improving Lives" - Members shared stories of how innovators and creators, including in partnership with governments, have used IP to address global challenges. Examples included healthcare products to provide faster diagnosis and better treatments; digital solutions to reform healthcare services; agricultural technology to help farmers significantly increase yields; and technology development projects either applied or developed in countries for which assistance is most needed, to name a few. Another key discussion point was the need to improve the awareness of, and accessibility to, IP systems to help a wider range of people harness the power of IP.

189. Third, under the sub-theme - "Intellectual Property and New Business" - Members stressed the importance of creating an IP environment in which SMEs and starts-ups can thrive by using the benefits afforded by trade secret, patent, trademark and copyright protections. Noting the significant

impact SMEs and start-ups have on their economies, Members expressed the need to increase IP awareness and provide IP counselling at the early stages of business development and innovation.

#### Research and Development (R&D)

190. Turning now to this session's theme - "Public-Private Collaborations in Innovation - Research and Development (R&D)" - I intend to highlight the importance the United States places on research and development to solve today's challenges, as well as the funding levels and mechanisms that move innovation to commercialization for the benefit of the public.

191. The United States government spends upwards of USD 150 billion annually on funding research and development conducted by universities, government research institutions, private businesses and individuals.

192. The federal government funds roughly 50% of academic research in the United States, and universities are the second largest performer of US R&D, after the private sector.

193. University research is crucial for advancing science and for expanding the knowledge pool, not to mention the viability and sustainability of our economy.

194. In addition, the transfer of technology from universities and other research institutions, which is normally early-stage research, to industry for further development and commercialization, is vital for maximizing the benefits of publicly funded research.

195. Patenting of inventions is critically important for licensing, securing investment and forming partnerships that lead to the commercialization of inventions. In the absence of a strong patent system, most of these inventions will never see the light of day because of the significant costs associated with the transformation to marketable products. In the absence of strong patent protection, investment in early-stage inventions would be too risky for businesses.

196. In the United States, technology transfer from universities to the private sector is made possible in large part by legislation commonly known as the Bayh-Dole Act, which was enacted in 1980, and became effective on 1 July 1981. It represented a fundamental change in US government innovation policy.

197. Bayh-Dole gives universities and companies the option to own inventions they develop with federal funding, and to grant exclusive licenses on those inventions.

198. Prior to the enactment of Bayh-Dole, recipients of federal funding, including universities, generally could not own title to publicly funded inventions. Federal agencies that provided funding retained all IP rights and could only grant non-exclusive licenses to private companies. In fact, at the time Bayh-Dole was enacted, the federal government held title to approximately 28,000 patents, of which fewer than 5% were licensed to industry for development of commercial products. Companies were reluctant to invest in developing new products and markets, since competitors could later acquire licenses from the Government and then manufacture and sell the same products. This meant that American taxpayers were not getting the full benefit from the billions of dollars invested in cutting-edge research.

199. The Bayh-Dole Act clearly changed that landscape. Universities are now encouraged to collaborate with industry to translate research results into products that benefit the public. Because the funding for the research comes from US taxpayers, by policy, preference is given to small businesses and to those making products in the United States.

200. Under Bayh-Dole, any income that universities receive from licensing must be used for rewarding university scientists and supporting the cycle of innovation.

201. The objectives of Bayh-Dole are to encourage maximum participation of small businesses and non-profits in federally funded R&D efforts, to promote collaboration between businesses and non-profits, to ensure that the Government retains sufficient rights from federally funded inventions to meet its needs, and to encourage the use of inventions for public benefit.

202. Bayh-Dole also includes a number of safeguards designed to protect the public interest. They include:

- a. Obligations to disclose each new invention to the federal funding agency, to make a decision whether or not to retain title to the invention and to file an initial patent application within a certain time period;
- b. A government use license that confers a non-exclusive, non-transferable, irrevocable, paid-up right to practice or have practiced the invention on behalf of the US government throughout the world, and other important safeguards; and
- c. Preference for SMEs for licensing purposes.

203. Robust university research, coupled with the enabling legal environment created by the Bayh-Dole Act, spawned entire new industries in the United States, such as biotechnology, where the United States continues to have a leadership role.

204. In the past 25 years, more than 11,000 start-ups have formed based on the results of university research. A majority of these were located in close physical proximity to universities, contributing to the local and state economy and development.

205. Let me provide a brief history of one of those start-ups.

206. The amount of information we are able to harness from the Internet seems limitless at times. In the mid-1990s, Stanford University doctoral candidates Sergey Brin and Larry Page were working on an algorithm that utilized all the links of different webpages to search and rank websites from the World Wide Web. At the time there were roughly 250,000 websites, compared to today where there are close to 2 billion. They initially called the engine Page Rank, but later changed it to the numeral "1" followed by 100 zeroes - or Google, as we know it today. This research was funded in part by a National Science Foundation grant.

207. Brin and Page were just a few of the many computer scientists that the National Science Foundation looked to for researching ways in which massive amounts of data could be managed for both government and commercial purposes. The federal government identified early on the benefits to national security of being able to manage such large databases; and we all know what became of Google. It currently has a market cap of USD 771 billion, and its revenue previous year was USD 136 billion.

208. Federally funded university research also ignited the innovative engines of Qualcomm, Symantec and Netscape, among many others.

209. In 2016 alone, 1024 start-ups were formed and 800 new products originating from university research were introduced to the marketplace by companies in the private sector. Over 200 new drugs and vaccines were developed through public-private partnerships since enactment of the Bayh-Dole Act.

210. Moreover, university technology transfer creates billions of dollars of direct benefits to the US economy and supports millions of jobs every year. One study found that between 1996 and 2013, academia-to-private sector patent licensing across all industries bolstered U.S. GDP by up to USD 518 billion and supported up to 3,824,000 U.S. jobs.

211. Additional legislation from the 1980s sought to achieve national technology transfer goals by requiring federal laboratories to have a formal technology transfer programme and to actively seek opportunities to transfer technology to industry, universities, and state and local governments.

212. Moreover, a collaborative mechanism was created to encourage federal agencies and laboratories to work with universities and companies toward a common goal. A Cooperative Research and Development Agreement, or CRADA, is an agreement between a Federal laboratory and a non-Federal party (US or foreign) to perform joint research and development in any area that is consistent with the Federal laboratory's mission.

213. Under a CRADA, a Federal laboratory may provide personnel, services, facilities, and equipment, but no funds, to the joint R&D effort. A non-Federal party may provide funds, in addition to personnel, services, facilities, and equipment.

214. A CRADA defines the tasks to be undertaken within an area of collaboration and grants the Federal government a government-purpose license and the non-Federal party a non-exclusive, paid-up, royalty-free license for internal use of any patents that result from the CRADA research.

215. The non-Federal party is also granted an option to negotiate either an exclusive or a nonexclusive commercial license within a field of use, subject to government-purpose rights. CRADAs also provide protection of proprietary information.

216. In practice, a federal agency - such as the National Institute of Standards and Technology - solicits the research community (universities, companies, and others) for collaboration in a particular area of research. A recent example of a solicitation involved tattoo recognition technology, which potentially has both government - law enforcement and national security - as well as commercial applications.

217. The United States' experience with collaborative research and development has been a good one. Important legislation such as the Bayh-Dole Act, the Federal Technology Transfer Act, and others allow federal agencies and laboratories, academia, and industry to work together on worthy causes - whether it is a vaccine, a diagnostic tool, or the technological seed that will grow into the next great start-up.

218. We look forward on hearing other Members on this topic.

## **11.2 Singapore**

219. Singapore, on behalf of co-sponsors Australia; Canada; Chile; the European Union; Hong Kong, China; Japan; the Republic of Korea; New Zealand, Singapore; Switzerland; Chinese Taipei; and the United States of America, is pleased to introduce our paper on the 2019 IP and Innovation overarching theme on "Public-Private Collaborations in Innovation".

220. Collaborations harness different expertise and resources across various sectors to develop new innovation breakthroughs that may not be possible in solo endeavours. In particular, strong collaborations between the public and private sectors are important for effective innovation to help address global challenges. The public sector (e.g. public research and research-funding agencies) and the private sector (e.g. research and development (R&D), manufacturing, and marketing and distribution companies) possess different resources, expertise and risk profiles that can complement each other to create IP and deliver useful innovative solutions that benefit society.

221. TRIPS Council Members are invited to take part in a three-part exchange this year and to share success stories on how public-private collaborations in innovation helps to improve lives, build resilient communities and create good jobs. As per the paper, three subthemes will be discussed at each of the TRIPS Council sessions this year, namely a) R&D – collaboration frameworks / building capacity and engaging in R&D; b) Innovation in Creative Industries and Branding; and c) Commercialisation. The latter two topics will be expanded upon in the respective TRIPS Council sessions in June and November respectively.

### **Public-private collaborations in R&D**

222. Focusing on the first theme, public-private collaborations in R&D can take various forms, depending on the specific situation.

223. One example from Singapore for illustration is Project Wolbachia, which is spearheaded by the Environmental Health Institute ("EHI") of our National Environment Agency ("NEA"). This project fights dengue in Singapore by developing technologies to control the *Aedes aegypti* mosquito population. Male Wolbachia-infected mosquitoes are released to mate with urban female *Aedes aegypti* mosquitoes, resulting in eggs that do not hatch. For this project, EHI is partnering a local start-up, Orinno Technology Pte. Ltd. ("Orinno"), and Verily, the life sciences and healthcare company of Alphabet Inc. EHI worked with Orinno to develop various automated devices to count

the larvae and pupae of Wolbachia-infected mosquitoes. With Verily, artificial intelligence technologies were developed to sort and release the male Wolbachia-infected mosquitoes efficiently.

224. In this regard, the Singapore Government has developed a standard framework on IP management in public-private collaborations to guide such collaborations. We also have initiatives to help businesses, in particular the small- and medium-sized enterprises ("SMEs"), acquire R&D expertise.

#### Standard Framework on IP Management

225. How IP created from R&D can be used would invariably depend on the ownership of the underlying IP rights and terms of use. In determining the allocation of IP rights in public-private collaborations, various considerations have to be borne in mind. For example, the private sector is generally better placed to further develop and commercialise the IP to meet market needs.

226. Therefore, in April 2018, Singapore implemented the National IP Protocol for Publicly-Funded R&D. This is a standard framework for how IP generated from publicly-funded R&D should be owned, managed and exploited, so that the value of the IP can be fully exploited to benefit Singapore. This framework allows public agencies the flexibility to grant licences or assign IP to the industry, with the goal of facilitating IP commercialisation.

#### Helping Businesses Acquire Expertise

227. In some cases, businesses may not have the technical expertise to conduct further R&D to develop solutions to meet the needs in the industry or community, but such expertise can be found in public sector R&D agencies.

228. Singapore's public research agency, the Agency for Science Technology and Research ("A\*STAR"), has a few programmes to help the private sector acquire and develop R&D expertise. One such programme is the Technology for Enterprise Capability Upgrading ("T-Up") Scheme, where A\*STAR will second researchers to companies to help build up their in-house R&D capabilities. Since the launch of the scheme in 2003, over 678 SMEs have benefited. Another programme is Tech Access, where A\*STAR helps SMEs access expert training. This enables enterprises to prototype new products and improve their manufacturing capability. Since the launch of this programme in 2017, over 30 companies have been supported.

#### Conclusion

229. Singapore values public-private collaborations in R&D. Done well, they deliver innovative solutions to benefit society and create good jobs.

230. We look forward to hearing from other Members on their experiences in facilitating public-private collaborations in R&D.

### 11.3 Australia

231. Australia has long recognized the value of collaboration between the public and private sectors in promoting innovation, and the Australian government has in place a number of programmes aimed at helping the two sectors work together.

232. One example is the Cooperative Research Centres Program, or CRC.

233. The CRC Program provides grants for up to ten years to support industry-led partnerships between industry and research bodies. It is organised along sectoral lines and is designed to address specific challenges identified by individual industries.

234. To qualify for funding, Cooperative Research Centres must include at least one Australian industrial entity and one Australian research organisation. There is no set funding limit for the Centres.

235. A second stream of the program, known as CRC-Projects (CRC-Ps), provides funding of up to AUD 3 million for a maximum of three years for industry-led collaborative research. CRC Projects must involve at least two Australian industry entities (including at least one SME) and one Australian research organisation.

236. The Australian Government has committed AUD 731 million to the CRC Program over the next four years, and there are currently 113 collaborative projects under way. Over the programme's lifetime, the government has provided AUD 4.6 billion in funding, while programme participants themselves have contributed a further AUD 14.1 billion, supporting a total of 316 projects.

237. The CRC Program has paid handsome dividends, with an independent evaluation conducted in 2012 concluding that it delivered a 3:1 return on investment.

238. Examples of the programme's more notable success stories include:

- a. The development of longer-lasting insulated rail joints (devices used to monitor trains and detect damage to railway tracks) that have produced annual savings of AUD 30 million for the rail industry;
- b. Productivity improvements of AUD 65.3 million resulting from the use of products developed by a cooperative research centre for polymers; and
- c. Approximately AUD 120 million in additional earnings flowing to Australian hearing aid pioneer Cochlear, after it adopted new technology developed by yet another Cooperative Research Centre.

239. Another important programme is the Research and Development Tax Incentive. This programme lowers businesses' R&D costs by offering annual tax offsets of up to AUD 100 million for eligible R&D expenditure and providing eligible small and medium-sized enterprises with a cash refund if they make a loss.

240. The tax incentive programme seeks to address the obstacles that many Australian companies face in raising finance for R&D activities in an environment in which success is far from guaranteed, and innovation can inadvertently benefit competitors. It therefore sustains a range of productive R&D activities that would otherwise remain on the drawing board.

241. I would like to turn now to some of the specific issues identified by Singapore in its discussion paper which Australia has co-sponsored along with other delegations.

242. First, how do we balance our support for innovative businesses with accountability for the use of public funds? Australia employs a range of checks and balances to ensure that tax payers' money is spent responsibly. Industry support programmes are evaluated under the Department of Industry, Innovation and Science's Evaluation Strategy 2017 – 2021, which provides a framework to guide the evaluation and performance assessment of the Department's programmes and policies.

243. As already noted, applicants for funding under the CRC Program must meet strict eligibility criteria, while companies claiming the R&D tax offset must also meet certain requirements.

244. Second, how should we manage the IP that results from collaboration between the public and private sectors?

245. It goes without saying that collaborations of this kind can be quite challenging, due to the complex intersections between confidentiality, the use of pre-existing IP, the publication of research findings, commercialisation, and decision making around IP rights. Recognizing these complexities, Australia's IP Office, IP Australia, strongly advises would-be collaborators to give due consideration to IP management issues before embarking on joint research projects.

246. IP Australia has developed a variety of tools that are publicly available on its website, ranging from collaboration checklists, to model confidentiality agreements.

247. Finally, how can government agencies help the private sector capture and develop expertise in R&D, and acquire IP?

248. In recognition of its growing importance to the development of innovation frameworks, knowledge acquisition and promotion of entrepreneurship, IP Australia has introduced a number of initiatives aimed at supporting collaboration between research organisations and the business sector.

249. The Australian IP Toolkit for Collaboration (IP Toolkit) is a joint project between the Department of Industry, Innovation and Science and IP Australia, designed to facilitate collaboration between researchers and industry.

250. The IP Toolkit contains background information, guides and a range of tools –such as model contracts - that researchers and businesses can draw upon to help them manage IP arrangements in a collaborative setting.

251. Another initiative developed by IP Australia is Source IP, which connects businesses with Australian public sector research organisations seeking to license their patented technology. Source IP was launched in November 2015 and is particularly focused on making it easier for Australian businesses, including micro-, small- and medium-sized businesses, to access innovations and technology generated by the publicly funded research sector in Australia.

252. The Source IP site has generated a substantial amount of interest, attracting users from a number of countries and recording over 200 contact requests to date. While Source IP does not currently list international patents, IP Australia has been discussing with overseas counterparts the possibility of expanding the platform by providing a link to their equivalent sites on Source IP or granting access to Source IP in their own jurisdictions.

253. Source IP has already made an impact. It was, for example, instrumental in the successful collaboration of a small Australian tech start-up called Forcite Helmet Systems with the University of New South Wales (UNSW).

254. Forcite is developing the world's first smart helmet, embedding communications systems into light recreational sports helmets and streamlining communications systems used by motorcycle emergency services.

255. Through Source IP, Forcite gained access to patents held by UNSW and has now integrated a UNSW patent into its helmet design.

256. Another initiative helping Australian businesses bolster their R&D expertise is the Entrepreneurs Program, which consists of two strands, Accelerating Commercialisation and Innovation Connections:

- a. Accelerating Commercialisation helps eligible entrepreneurs, start-ups, small to medium-sized businesses and researchers to commercialise their novel product, process or service. By providing expert guidance, connections and financial support, it helps to bring fresh innovations to market as quickly as possible, increasing their prospects for success; and
- b. Innovation Connections is a facilitation service that provides expert advice and solutions on knowledge-related issues, and a brokering service to connect businesses with knowledge providers and research organisations. This may include a matched funding grant that assists with direct access to research facilities.

#### **11.4 Switzerland**

257. Switzerland would like to thank Singapore for proposing and introducing this TRIPS Council agenda item. We are pleased to co-sponsor both the agenda item and submission IP/C/W/652.

258. We welcome the opportunity to exchange national experiences and hear about different approaches in the highly relevant area of public-private collaboration in innovation.

259. The question is: How can the public and private sectors interact to establish an innovative environment? The role of intellectual property rights is of particular importance to this kind of collaboration: A well-regulated and balanced distribution of rights and obligations significantly enhances cooperation and innovation. The aim is to ensure that public sector research complements rather than substitutes private sector research. Such collaboration should result in an enhancement of the social value of IP and the patent: innovation and technology are developed into marketable and socially useful products.

260. My delegation would like to present how Switzerland establishes interfaces between the public and private sector and point out the role that intellectual property plays in this collaboration for the development of new products and services.

261. The Swiss Constitution instructs the Confederation to promote innovation. It is for the federal authorities and the parliament to put in place the legal framework, without taking control over the direction of research chosen by private actors. Federal bodies may support start-ups with advice, to a limited extent with seed-funding, or may make available certain infrastructure which can facilitate young entrepreneurs' activities and endeavours, for example in the form of technology parks.

262. Platforms of public-private collaboration facilitate the exchange of knowledge and generate synergies. They enable innovation and access to technology across the society. Technology is transferred from academia and researchers to applied research and industry and from there to the consumers. Building the bridge between basic and applied research, public-private partnerships enable social and economic investment in R&D and allow for economic growth.

263. In the following, I will present two types of public-private cooperation practiced in Switzerland. The first type of partnership arises when a private actor has a patentable invention but lacks the means to develop the idea into a marketable product. This is where the public sector can come in as a facilitator. Let me illustrate such a collaboration with an example of the development and market launch of an innovative food preservation technology.

264. Writing her doctorate, Olga Dubey, a young biologist, discovered a natural substance that can be used to combat pathogenic fungi which infest fruit and vegetable. She knew that up to that day there was no efficient, cost-effective organic treatment against moulds on the market. As Ms Dubey became aware of the market potential of her discovery, it was also clear that she needed help in the form of advice and funding in order to develop her scientific discovery into a marketable product. She decided to apply for participation in the federal programme called "BRIDGE". Literally functioning as a bridge between research and practice, the programme was initiated in December 2016 by the Swiss National Science Foundation and Innosuisse, the federal innovation promotion agency. Today, more than 40 projects benefit from the collaboration platform. By means of enhancing knowledge transfer between research and entrepreneurship, BRIDGE supports researchers in developing their discoveries into concrete applications and marketable products that can be used for the benefit of society.

265. Thanks to BRIDGE's support, Ms Dubey ventured the step from science into her own business. The collaboration platform allowed her to go through the process of filing for a patent and setting up her own start-up, AgroSustain SA, while further enhancing her research activities. The young company developed a liquid which can be sprayed or fogged on crop yields, extending their shelf-life.

266. The post-harvest application of AgroSustain's liquid in food and plant storage facilities enables a significant reduction of waste. This also means a major reduction of greenhouse gases, an additional effect of less food spoiling along the supply chain. AgroSustain's product is going to be offered to major agricultural companies and retailers like Migros in Switzerland or Walmart in the US. Without the guidance, coaching and funding support obtained, Olga Dubey would have been forced to continue keeping herself busy in the university laboratory – and the product would not be made available to society today.

267. Now, let us turn to the second type of public-private collaboration: In the following example, it was a public sector actor that applied for a patent, but was not able to commercialise the invention. It is an example which shows how the help of private actors can come in for the successful completion of a project initiated by a public institution.

268. The success story of the present case is the result of a partnership between EMPA, the Swiss Federal Laboratories for Materials Science and Technology, and Flisom Ltd, a Swiss developer and manufacturer of photovoltaic solar cells. In 2011, EMPA succeeded in the development of flexible solar cells. The thin film cells showed an energy efficiency similar to that of conventional solar cells. Although the patented technology had great economic potential, the research team would not have been able to set up a production plant and launch the product on the market without the help of an industrial partner. Against this backdrop, EMPA started cooperating with Flisom. Using EMPA's patented technology, the research team, combining scientists and industrial experts from EMPA and Flisom, improved the energy efficiency to a level equal to some of the most efficient solar cells in the world.

269. In 2015, Flisom was eventually able to produce a prototype of the first solar module based on this technology. The ultra-thin solar cells are printed on a web of flexible foils which allows for a very space-saving and cost-effective production. The company designed a special industrial manufacturing technology for a so-called "roll-to-roll production" of the flexible solar modules. The manufacturing procedure makes use of the material's characteristic. Compared to traditional large-scale solar panel windows, the new foil can easily be unwound, processed and finally rewound. Only one year later, in 2016, Flisom put its pilot production line into operation and started to install the new product on buildings, use it as an energy source for means of transport and integrate it in off-grid installations.

270. This example shows how important private sector actors can be in transforming an invention into a marketable commodity, for the benefit of society. As important as private investors are for the development of market-ready products, as in some areas of technology such development requires massive investments in time and resources. For small start-ups or young researchers, it is often difficult to raise enough money for the commercialization of their invention. At this point, a private or public partner can come in and act as decisive support, so that the momentum gained in early-stage research and development is not lost.

271. There are many other BRIDGE and EMPA projects which can serve as examples of effective cooperation and mutual support, where public-private partnerships turned ideas and work into marketable products suitable for mass production. The registration and management of patent, trademark and design rights supports such public-private ventures by putting their collaboration on a safe legal base. They help ensure that each partner receives a fair share of what each of them contributed along the innovation process, and if a commercial success results, of the profits made.

272. Oscar Wild once said: "The world is divided into two classes, those who believe the incredible, and those who do the improbable." Public-private collaboration in innovation can bring those two groups together, supporting the innovation process for the benefit of technological progress and economic development.

### **11.5 New Zealand**

273. New Zealand is pleased to be a co-sponsor of the Intellectual Property and Innovation 2019 Paper.

274. New Zealand recognizes the importance of maintaining collaborative synergies between the public and private sectors in order to promote innovation and creativity for the benefit of society.

275. To this end, the New Zealand Government has committed to raising New Zealand's research and development expenditure to 2% of our GDP over the span of ten years.

276. New Zealand has two devoted government agencies committed to improving innovation and to supporting private sector businesses in establishing and maintaining sustainable growth.

277. The first of these agencies is Callaghan Innovation. Callaghan Innovation has a domestic focus and offers a range of services and tailored programmes to businesses, including:

- a. Access to experts;
- b. Technology and product development;
- c. Innovation skills;

- d. Business collaborations; and
- e. Research and development grants.

278. Furthermore, New Zealand Trade and Enterprise is an international business development agency whose purpose is to help New Zealand businesses to grow internationally. It offers a range of services and tailored programmes to assist businesses to export and expand into new markets. It also promotes New Zealand to foreign businesses and investors, as well as helping businesses and investors to make international connections and mutually collaborate across international borders.

279. We look forward to hearing other Members' experiences on public-private collaborations in innovation.

### **11.6 Chinese Taipei**

280. As the co-sponsor of this proposal, we would very much like take this opportunity to share with you our own particular thoughts and experiences on this subject.

281. In this age of the "knowledge-based economy", innovation and application are the keys to strengthening national competitiveness and economic growth. Both the public and the private sectors possess different resources and expertise, which, when combined, can complement each other and create market-oriented IP. This has become a crucial issue as WTO Members strive more and more to develop innovative technologies.

282. With a view to getting colleges, universities and academic institutions to conduct R&D programmes together, we launched in 2013 the PIONEER Grants for AIC (Academia-Industry Collaboration) project. Through providing grants for research and development, this project has been able, at the same time, to encourage local businesses and academic/research institutions to develop forward-looking technologies together. And, the operative word here is "together". Businesses take the initiative to form alliances, decide on the topics for the research and invite academic and research institutions to build teams to carry it out. In doing so, it is hoped that they will acquire the ability to expand their key patent portfolios, establish new standards for the industries and integrate the different systems.

283. Since the launch of the PIONEER Grants for the AIC Project, industry has invested up till now TWD 2.16 billion (that is about USD 72 million) of R&D funds and filed as many as 515 patent applications. A total of 3,170 doctoral students have been trained, with 900 people obtaining new jobs.

284. In addition, in few years ago, we also launched the A+ Industrial Innovation R&D Program, subsidizing companies that are devoted to high-level R&D work. This includes a sub-programme on forward-looking technologies, which encourages companies and research institutions to develop leading technologies together. Our aim here has been to greatly increase industry's profit and competitiveness in the global market.

285. For example, the Garmin Corporation, which is a well-known tech company in GPS product, was awarded the project's subsidy for its "3D City Navigation System Development and Integration" plan. It was therefore able to compile a high-quality 3D city map for in-car navigation systems. Since then, the value of Garmin Corporation's production has reached TWD 1.4 billion (or USD 45 million).

286. Back in 1999, we launched the Small Business Innovation Research (SBIR) Project, to provide subsidies to SMEs for conducting R&D projects. The Project's main aims were to promote the research and development of industry technologies, products and services among SMEs, and to guide SME investment in R&D activities in the electronics, data communications, machinery, services, consumer goods/chemical, biotechnology/pharmaceutical, digital content, and design industries. In addition to applying for subsidies individually, SMEs are themselves encouraged to form R&D alliances together with universities and research institutions. The Project aims to cultivate R&D talent among SMEs in order to accumulate R&D capabilities, and to elevate the technological level of SMEs in order to increase the competitiveness of their businesses. It helps traditional industries to transform and advance as well.

287. By 2018, on the basis of the SBIR programme, 241 projects had received a total of TWD 310 million (or USD 10 million) in subsidies, and this had led to TWD 520 million (USD 16.7 million) worth of R&D investment by our SMEs.

288. One such project worth mentioning here, just as an example, was for the research and development of decorative flame products. Before implementing the SBIR subsidized project, it was only the companies that possessed the innovative technologies for flame products. But, upon forming technological alliances, the companies were finally able to develop advanced decorative flame products and have since obtained more than 30 patents in Europe, the USA, Mainland China and in our own territory. They have also built their own brands and made their way into the international market.

289. So, it goes without saying that IP and innovation are critical to any WTO Member's economic growth. It is, therefore, a crucial task of the government to assist their public and private sectors in developing innovative technologies, based on their own resources and through comprehensive strategies.

290. I hope this has given you some useful examples of what can be achieved by encouraging the different sectors and elements in our economies to work together on the crucial issues of innovation and technology facing us all in the future.

291. We look forward to hearing from other Members about their own related experiences and measures taken in similar fields.

### **11.7 Chile**

292. We thank the co proponents of this document and agenda item for providing us with the opportunity to share our country's successful experiences. The Government of Chile has prioritized public-private partnerships as a tool to promote innovation.

293. The Chilean Economic Development Agency (CORFO) is a government agency with the legal mandate to support entrepreneurship, innovation and competitiveness. In order to fulfil this mandate, CORFO has developed strategic support plans for scientific industrial consortia.

294. Lastly, we would like to point out that these initiatives have highlighted the importance of ensuring that intellectual property management strategies are consistent with the business models of companies participating in such projects. The success of these public-private partnerships has been possible thanks to dialogue between the parties concerned, which ensures that the particular needs of each project are understood and that the capacities generated are beneficial to the country's innovative ecosystem.<sup>1</sup>

### **11.8 South Africa**

295. During 2018 the co-sponsors discussed the topic of 'Societal Value of IP in the New Economy'. South Africa actively participated and expressed its views on several sub-topics of this theme as introduced by the co-sponsors.

296. In respect of IP-intensive industries and their impact on society, co-sponsors presented "evidence" that IPRs contribute to employment, gross domestic product, licensing revenue and trade. However, a closer look at the statistics indicate that a purely economic approach to IPRs may be misleading given that co-sponsors focus on the societal benefit of technological innovation.

297. The effect of IPRs on economic growth in different countries depends upon their various stages of development (being measured in terms of per capita GDP growth and/or human-capital development); innovative capability and imitative activities; technological development; and factor endowments, etc. In general, due to different R&D activities, most the innovations are produced in high income countries. Furthermore, economic literature on the impact of IPRs is rather inconclusive. It remains ambivalent as to whether the social benefits of IPRs exceed their economic costs, even in relation to the developed world. The basic argument in favour of IPRs is that they are necessary

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<sup>1</sup> The PowerPoint presentation is available in Room Document RD/IP/31.

to stimulate invention and new technologies. The main critique against IPRs is that they increase the cost of patented commodities which reduces welfare. This problem is exacerbated in developing countries because they are net importers of technology. Indeed, innovative activities are concentrated in a handful of developed country Members with the top ten countries accounting for 84% of global R&D activity.<sup>2</sup>

298. As already noted, many developing countries are large technology importers and developing countries that strengthened their IPRs protection (mainly in the 1990s) have significant negative balances on the royalty and license fees account. A 2016 study<sup>3</sup> concludes that IPRs tend to raise income inequality by generating a more skewed distribution of wages. Stronger IPRs increase the demand for skilled labour force as it raises the return on R&D activities. This causes a relative increase in skilled labour wages, creating a wage bias in favour of skilled labour against unskilled labour, thus aggravating income inequality within a developing country. Moreover, the effect on inequality is more pronounced for developing countries that are experiencing higher per capita GDP growth rates.

299. Proponents also advanced the argument that in respect of education and training, a range of intellectual property rich materials foster social and economic contributions to society. South Africa pointed out that a fundamental component of the right to education is access to high quality text books and other learning materials. Yet in many developing countries, access to such resources can be prohibitive since textbook scarcity is a serious challenge affecting the quality of education. We cited the example of an African country, where there is approximately one reading textbook available for every 12 grade-two students and one mathematics text book per 14 students.

300. Co-sponsors argue that as more and more learning is facilitated through computer access and the internet, both students and teachers are able to log onto fast amounts of information. Unfortunately, access to these technologies are both inadequately and unequally distributed between the developed and least developed regions in the world. The disparities experienced in the physical world, we pointed out, is often exacerbated in the online environment. The UNCTAD *World Development Report of 2018*, indicates that there are still-large gaps between developed and developing countries: the active broadband subscription in the developed world (at 97%) is more than double that in the developing world (48%); in Africa, only 22% of individuals use the Internet, as compared with 80% in Europe.<sup>4</sup>

301. While there is no doubt that IP may be valuable and may contribute to economic development and growth, there are many factors that determine whether IP protection may create appropriate conditions that enable MSMEs to effectively exploit IP.

302. In conclusion, South Africa has also indicated that we are reviewing our IP Policy, ensuring that appropriate balances are struck in providing protection for innovation and ensuring that benefits are shared equitably in society.

## 11.9 South Africa

303. We thank the co-sponsors for introducing the item of public-private collaborations in innovation.

304. South Africa followed a global trend in the popularity of Public-Private Partnerships (PPPs) by establishing a formal PPP structure within the National Treasury in 1999. Although there were PPPs prior to this date, these arrangements did not follow a standardised process or receive formal recognition as PPPs within the Nation Treasury Department of South Africa.<sup>5</sup> South Africa has implemented a regulatory framework for PPPs which came into effect in the early 2000s, enabled through the Public Finance Management Act of 1999 (PFMA). The National Treasury of South Africa

<sup>2</sup> See Auriol, Baincini & Paillacar "Intellectual Property Rights Protection in Developing Countries." July 2012 at p.2.

<sup>3</sup> Swati Saini & Meeta K Mehra "Impact of strengthening Intellectual Property Rights Regime on income inequality: An econometric analysis centre for international trade and development." <https://mpr.ub.uni-muenchen.de/75456/> MPRA Paper No. 75456, posted 10 December 2016.

<sup>4</sup> UNCTAD *World Development Report of 2018*, p.VIII.

<sup>5</sup> Walwyn and Nkolele "An evaluation of South Africa's public-private partnership for the localization of vaccine research, manufacture and distribution." Health Research Policy and Systems (2018) 16:30 p.3.

developed a standardised procedure for such an entity, which it defined as a "contract between a government institution and a private party, where the private party performs an institutional function and/or uses state property in terms of output specifications; substantial project risk (financial, technical, operational) is transferred to the private party; and the private party benefits through unitary payments from government budgets and/or user fees".

305. According to standard economic criteria, South Africa is a high-income country with a well-developed infrastructure, with nearly 70% of the population urbanised and deep and liquid capital markets. However, it is also one of the most unequal economies in the world with a post-tax Gini-coefficient of 0.7, with unusually high levels of structural unemployment (around 36%) and poverty (around 50%).

306. Initial PPP projects were undertaken between 1997 to 2000 by the South African National Roads Agency for the N3 and N4 toll roads (national roads), the departments of Public Works and Correctional Services for two maximum security prisons, two municipalities for water services, and by South African National Parks for tourism concessions. Using lessons from these projects, together with international experience, a strategic framework was adopted by government in December 1999 and in April 2000 in accordance with Treasury Regulations for PPPs issued in terms of the PFMA.

#### Examples of PPP collaborations

307. It is often said that vaccines are lauded as one of the most successful public health interventions, providing universal prophylaxis at a fraction of the cost that would otherwise be incurred following the widespread outbreak of an infectious disease. In the case of South Africa, an extensive vaccination programme, known as the Expanded Programme for Immunisation (EPI) forms part of a health strategy adopted by the National Department of Health (NDoH). Implementation of the EPI requires the procurement of approximately 46 million vaccine doses annually, at a cost of roughly ZAR 1.5 billion per annum (2015 values). Prior to 2003, vaccine procurement was an internal function of the NDoH; the department issued tenders on behalf of the provinces and secured the necessary supply from successful bidders. However, since 2004, vaccine procurement and distribution has been undertaken by a public-private partnership (PPP), known as the Biovac Institute (BI).<sup>6</sup>

308. Over the period 2010 to 2014, BI successfully procured and distributed vaccines and received an income of USD 86 million, equivalent to an average cost premium of 12%, as per the terms of its supply agreement with the NDoH. Moreover, it became increasingly able to supply vaccines to the public health system at globally competitive prices and undertook local R&D, the latter in one case leading to a novel conjugate vaccine that has been licensed to two international companies and for which the institute receives royalty revenue.<sup>7</sup>

#### 11.10 Hong Kong, China

309. Hong Kong would like to thank the United States and Singapore for introducing the papers under this agenda item which we are pleased to be a co-sponsor. I am also thankful to previous speakers sharing their experiences.

310. Hong Kong was glad to participate in the discussion of societal value of IP in the new economy in 2018. I hope our sharing in particular on how IP improves life did give Members some food for thoughts in promoting IP and innovation.

311. On the Public-Private Collaborations in Innovation, Hong Kong recognizes that R&D is essential in promoting innovation, new technology and intellectual property. All these are drivers for economic growth and the key to enhancing competitiveness of our industries. Our Government has therefore put in place a comprehensive framework of policies and institutions to promote R&D using the collaborative efforts of public and private sectors.

312. A key aspect is the provision of infrastructure that forms an enabling environment for R&D and an essential part of a strong innovation eco-system. We establish a publicly-funded statutory

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<sup>6</sup> Ibid.

<sup>7</sup> Welwyn & Nkolele p.15.

corporation, the Hong Kong Science and Technology Parks ("Science Park"), offering one-stop infrastructural support to technology-based companies and activities. It provides a comprehensive range of services to cater the needs of industry at various stages, ranging from nurturing technology start-ups through incubation programme, providing physical space and services for R&D activities, and to offering industrial lands for production.

313. As an example of public-private collaboration, the Hong Kong Government allocated about USD 1.3 billion to establish two research clusters - one on healthcare technologies, and another on artificial intelligence and robotics technologies - in the Science Park, in order to attract the world's top universities, research institutes and technology companies in the relevant fields to conduct collaborative research in Hong Kong. Numerous top-notch institutions e.g. Institute Pasteur of France, Harvard Medical School, Stanford University School of Medicine, and University College London, have already expressed interests in joining the clusters. It is expected that the first batch of scientific research institutions will be set up later this year.

314. We also have set up five publicly-funded R&D centres to drive and co-ordinate applied R&D in five focus areas, i.e. automotive parts; information and communications technologies; logistics and supply chain; nanotechnology and advanced materials; as well as textiles and clothing. The centres have been working closely with the industries in conducting industry-oriented R&D and promoting commercialisation of the R&D results. These R&D centres are core initiatives to upgrade the technological level of our industries and stimulate the growth of technology-based industries.

315. Hong Kong also strives to provide adequate funding to promote R&D in a direct and impactful manner. In particular, there are funding schemes to provide incentives for public and private collaboration. Just last month, we established a Partnership Research Programme by consolidating two existing funding programmes to provide matching-fund support for R&D projects undertaken by private companies in collaboration with public research institutions. To ensure sufficient participation from both public and private sectors, the public research institutions are required to be the lead applicant, while the private companies are required to provide at least 50% of the project cost (or at least 30% with exceptional approval from the Government). The companies are required to spend the funds in R&D only, but not in business development or operating expenses.

316. To encourage private companies to undertake more R&D projects, all IPR arising from the project will be solely owned by the companies having contributed at least 50% of the project cost. In case of exceptional collaborative projects involving less than 50% company contribution, the relevant R&D Centre should retain the IP ownership, and the company partner should only be granted an exclusive licence or exclusive right to use the R&D results for a limited period. With a view to boosting private companies' contribution, the R&D Centre would encourage its partner to raise the level of its contribution to at least 50% within a reasonable timeframe, say nine months, so that the latter could own the IPR.

317. We also launched another programme, the Cash Rebate Scheme, in 2010 to encourage private companies to establish stronger partnership with public research institutions. Under the scheme, a company will receive a cash rebate equivalent to 40% of its expenditure in projects under a major Government fund or other R&D projects funded by the companies and undertaken by public research institutions. As at end November 2018, around 1,200 companies have been granted cash rebate of more than USD 50 million.

318. While Hong Kong has a low profit tax rate (which is no higher than 16.5%), we provide enhanced tax deduction for private companies' expenditure on R&D activities which includes payments made to designated local research institutions. The deduction will be 300% for the first USD 250 000 of expenditure, and 200% for the remaining amount. There is no limit on the amount of enhanced tax deduction. We believe that this will encourage private enterprises to conduct R&D in collaboration with research institutions in Hong Kong.

319. In addition to funding, the private sector would look to talent to drive R&D activities. Hence our government is committed to supporting private companies in recruiting R&D talent. We rolled out the Technology Talent Admission Scheme in 2018. It provides a fast-track arrangement for admitting technology talent from overseas and Mainland China to undertake R&D work in Hong Kong. To balance the development and opportunity of local talent, we would require such companies to employ a certain number of local employees and interns in technology-related work.

320. We also launched a Technology Talent Scheme to pool together and nurture more technology talent for technology companies and institutions. It comprises a Postdoctoral Hub programme that subsidises government fund recipients and incubatees or tenants of Science Park to recruit up to two postdoctoral talent. Besides, there is another programme that subsidises local companies to train their staff in advanced technologies.

321. To assist private companies to acquire IP of their innovations, we launched an "IP Manager Scheme" in 2015. The scheme assists Hong Kong companies to build up their IP manpower capacity and to increase competitiveness through IP management. The scheme encourages enterprises to appoint a staff Member in a managerial position as their in-house "IP Manager". This IP manager is responsible for overseeing the compliance, management, exploitation and commercialisation of IP assets. The Hong Kong government would provide training and resources for those IP Managers.

322. To conclude, promoting innovation and technology is one of Hong Kong's top policy agenda. Our goal is to develop Hong Kong into an international innovation and technology hub. Knowing that the public and private sectors have different edge, we will keep devoting resources to facilitate public-private collaborations. We would also welcome collaborations with institutions from other Members.

### **11.11 Canada**

323. Canada is pleased to co-sponsor the "IP and Innovation" theme of "Public-Private Collaborations in Innovation", and the accompanying communication on this topic. We would like to thank Singapore for drafting the paper for discussion under document IP/C/W/652, as well as the co-sponsors of this discussion and other Members that have shared their national experiences and insights on public-private collaborations in innovation so far.

324. Before sharing some of our own recent experiences on this topic, Canada would also like to thank the United States and the co-sponsors of the summary paper on our recent discussions under the theme "The Societal Value of IP in the New Economy" (document IP/C/W/650). Canada was pleased to participate in the wide-ranging discussions under this theme during the three TRIPS Council meetings in 2018 and benefited from the constructive and insightful sharing of experiences by Members on issues such as IP-intensive industries, IP improving lives, and IP and new business.

325. On the Public-Private Collaborations in Innovation topic, Canada would like to take the opportunity to present an overview of Canada's recently-launched "Innovation Superclusters Initiative", a new funding initiative by the Government of Canada that has been designed to help strengthen Canada's most promising clusters and accelerate economic growth in highly innovative industries.<sup>8</sup>

326. In the Government of Canada's Budget 2017, the Government put forward the "Innovation and Skills Plan", an agenda to spark growth and help Canada realize its potential as a global leader in innovation. As part of this agenda, in May 2017, the Government launched the "Innovation Superclusters Initiative" to accelerate innovation through superclusters. Budget 2017 proposed to invest up to CAD 950 million (or approximately USD 725.51 million), to be provided over five years on a competitive basis in support of a small number of business-led innovation superclusters that have the greatest potential to accelerate economic growth. Under this initiative, industry partners match the Government of Canada's programme contributions dollar-for-dollar.

327. This initiative is a first of its kind for Canada, fostering connections between participants, from start-ups, small and medium-sized enterprises (SMEs) and large anchor firms, to post-secondary institutions, research and government partners. Through a small number of high-value, strategic investments, this initiative is co-investing with industry to strengthen Canada's most promising clusters and build superclusters at scale. The initiative is a "made in Canada" approach. Working through a business-led partnership model, the initiative works to align the efforts of diverse industries, researchers, and intermediary institutions, and build ecosystem-level advantages in regions across Canada.

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<sup>8</sup> The PowerPoint presentation is available in Room Document RD/IP/32.

328. Supercluster strategies under the initiative are structured around five themes of activity, which are eligible for co-investment. These activities include:

- **Technology leadership**, such as by way of collaborative projects that directly enhance Member firm productivity, performance and competitiveness (for instance, through collaborative R&D projects and private-sector-led commercialization projects).
- **Partnerships for scale**, which refers to activities serving a target group of cluster firms, such as linking start-ups with strategic partners, and supply chain development to cluster SMEs with anchor firms;
- **Diverse and skilled talent pools**, such as by way of activities that enhance regional labour force skills and capabilities;
- **Access to innovation**, which refers to investment in and providing access to assets, services or resources that benefit a range of cluster firms, such as the acquisition and assertion of jointly-held IP; and finally
- **Global advantage**, which refers to activities that position the cluster as world-leading, enabling firms to seize market opportunities, and attract international investments and partnerships.

329. One of the key objectives of Canada's Innovation Superclusters Initiative is to deepen existing strengths where Canada is already globally-competitive. This includes strategies to enhance Canada's capabilities, competitive advantage and leadership in commercialization. As well, the initiative is aimed at supporting industry-led collaborative R&D, particularly with respect to platform technologies, and to strengthen public-private collaboration, including with academia, to align innovative ecosystems.

330. In fostering a critical mass of growth-oriented firms, the initiative aims to develop five "superclusters", namely innovation hotbeds that benefit from strong connections between firms and research talent, competitive advantage, global brand recognition, and a contribution to job creation and economic growth.

331. The Minister of Innovation, Science and Economic Development announced Canada's five selected superclusters in February 2018. Following the national announcement, the negotiation of contribution agreements began between the Government of Canada and the five industry-led consortia selected to execute Canada's superclusters. Contribution agreements between the Government of Canada and all five Superclusters have been signed as of December 2018, and the superclusters are currently finalizing their five-year strategies, with project funding expected to begin before the end of the fiscal year (31 March 2019).

332. Now for a bit of a geography lesson, from West to East in Canada, the superclusters are:

- The *Digital Technology Supercluster* (based in British Columbia, with a key focus on technologies such as augmented reality; cloud computing and machine learning; data collection and analytics; and quantum computing);
- The *Protein Industries Supercluster* (based in Canada's Prairie provinces, this supercluster will use plant genomics and novel processing technologies to increase the value of key Canadian crops, such as canola, wheat and pulses, as well as plant-based meat alternatives and new food products);
- The *Advanced Manufacturing Supercluster* (based in Ontario, this supercluster is focused on building next-generation manufacturing capabilities, for instance, through the development of technologies like advanced robotics and 3D printing);
- The *SCALE.AI Supercluster* (based in the Québec-Windsor corridor, this supercluster focuses on artificial intelligence and robotics, with a view to helping Canadian SMEs scale up and become a globally competitive export leader), and
- The *Ocean Supercluster* (based in Atlantic Canada, this supercluster focuses on industries like marine renewable energy, fisheries, aquaculture, oil and gas, shipbuilding, and transportation, through the development of technologies such as digital sensors and

monitoring, autonomous marine vehicles, energy generation, and marine biotechnology and engineering technologies).

333. Together, these five superclusters represent more than 450 businesses, 60 academic institutions, and 180 partners in Canada's five key regions.

334. Under Innovation Supercluster Initiative, funding is provided to industry-led consortia (which include large firms, as well as SMEs, and other organizations such as academic and research institutions). Under these arrangements, funding is provided to Entities with strategic plans to: build a shared competitive advantage for their cluster and attract research, investment, and talent; increase business expenditures on R&D and advance business led-innovation and technology leadership; generate new companies and commercialize new products, processes and services; and foster a critical mass of growth-oriented firms and strengthen public-private-academic collaboration.

335. These strategic plans are built on a shared private sector commitment, demonstrated through matched, dollar-for-dollar industry funding, to leverage strengths, address gaps, and bring innovation ecosystem players together to work more strategically. In doing so, it is expected that superclusters will engage in collaborative projects and activities that advance their respective goals, and develop innovative new technologies that address ecosystem gaps.

336. As part of its strategic plan, each Entity also submits an IP Strategy, which sets out its role in achieving programme objectives through IP-related activities. In particular, each Entity's IP strategy sets out how protection for Entity-supported IP will be obtained, how rights will be owned and managed, and by whom. This also includes how background IP will be treated; if and how non-Entity-supported IP will be acquired; and how royalties on Entity-supported IP will be managed. The IP Strategy also sets out how the IP ownership and management structures furthers each Entity's objectives.

337. In addition, the IP Strategy sets out the policies for Members' access to Entity-supported IP, and how Members will be supported and mentored in respect of their IP needs. One of the key objectives in this regard is to provide that Entities proactively engage their Members and provide access to independent expertise and mentorship concerning IP-related issues, particularly in respect of start-ups and SMEs. This includes assistance with IP development, registration, acquisition, management, ownership, royalties, and assertion of legal rights.

338. In developing the Innovation Superclusters Initiative, the five superclusters are not only expected to contribute to economic growth in Canada, but also represent strong links in global value chains, which deliver high-quality Canadian products and solutions. Multinational enterprises that are incorporated and active in Canada are eligible to collaborate and partner with existing supercluster organizations, with a view to accessing Canadian innovation and technical expertise, with a number of global firms already involved.

339. With that in mind, we would be pleased to provide further information regarding the Innovation Superclusters Initiative upon request, as well as by directing questions to our experts at Canada's Department of Innovation, Science and Economic Development.

340. To conclude, Canada would like to once again thank Members for sharing their national experiences in respect of public-private collaborations on innovation with TRIPS Council, and for the opportunity to present an overview of this initiative.

#### **11.12 Japan**

341. First of all, this delegation would like to thank the distinguished delegation from US for summarizing the discussion in the previous year. And this delegation would like to review that discussion briefly as well. Throughout 2018, we shared each experience and national or international policies, and not only developed country Members but also developing countries provided empirical data and case studies showing positive impact of IP on innovation. As we have seen in the discussion, to certain extent, we have the common perception that IP contributes to improving the quality of life and creates essential condition for SMEs and start-up to succeed. This delegation believes that recognizing common experiences and views helps us to properly understand the role of IP system and to find appropriate direction of its future development.

342. This delegation would like to share our experience and national policies regarding public-private collaboration in innovation. Especially, we would like to focus on ownership of patents in the collaborative R&D project funded by government and show you some survey results in Japan.<sup>9</sup>

343. First, we will show you the collaboration framework in R&D project funded by government in Japan. In general, it is said that private sector tends not to invest sufficiently under the high uncertainty situation. This delegation believes that public sector can play a key role in encouraging and supporting private sectors in such a case. Japanese government implements commissioned R&D projects in order to complement underinvestment on the R&D projects by using public fund. And commissioned R&D projects involve private companies so as to achieve the maximum use of outcomes of R&D projects.

344. In this projects, ownership of patent rights should be considered with the view to promote effective utilization of the results of such a R&D project. Who should own patents obtained through commissioned R&D projects? Article 19 of Industrial Technology Enhancement Act in Japan stipulates that the national government may decide not to accept patent right pertaining to the result of R&D entrusted by the government from that entrusted party.

345. Therefore, government may decide whether government owns patents or trustees' own patents.

346. In this slide, this delegation briefly shows you two different scenarios regarding to commercialization process.

347. First, in case where trustees' own patents, trustees will engage in the commissioned R&D projects and conduct continuous R&D after projects with expectation of return of R&D investment and secure profit by exclusive implementation.

348. On the other hand, in case where government owns patents, trustees will engage in the commissioned R&D projects in expectation of obtaining know-how and first-mover advantage, and after the project, not only trustees but also third parties will consider pros and cons to challenge the commercialization of the outcomes. And each company exerts their respective strengths to utilize the outcomes of the project in diverse form of applied products and services. Competition among companies will provide inexpensive products and services as well.

349. In both scenarios, outcomes of R&D project will be returned to the whole society through supplying products and services based on the technologies established in the commissioned R&D projects.

350. According to the survey, utilization rate of patents owned by trustees are larger than that of patents owned by government. It reveals only 2.5% of patents owned by government are utilized, while 20.4% of patents owned by trustees are utilized. And even definition of term "utilized" in case where trustees' own patents includes present and future self-implementation and license, 8.0% out of 20.4% patents are utilized in "present" self-implements or license.

351. Therefore, the survey indicates clearly that the mechanism of making it possible to own patents foster utilization of patents of the industrial commissioned R&D project.

352. Finally, this delegation would like to show you main factors affecting the utilization rate of patents.

353. In case where trustees' own patents, possibility of owning patents incentivizes trustees to deeply engages in the commissioned R&D project and enhances an trustees' incentive for acquiring patents with a view of commercialization and ensures an incentive for commercialization after the end of commissioned project. In addition, trustees who own patents are likely to utilize the outcomes of R&D project efficiently, that is partly because they are able to streamline technology transfer by licensing patents in along with relevant know-how and technical guidance.

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<sup>9</sup> The PowerPoint presentation is available in Room Document RD/IP/30.

354. On the other hand, in case where government owns patents, patent applications are likely to be filed without a view of commercialization, and when government license patents, usually relevant know-how and technical guidance are not available for licensees.

355. In summary, this delegation would like to emphasize again that the mechanism of making it possible to own patents incentivizes trustees to engage in R&D project funded by government and to commercialize with continuous investment by themselves, and it improves the utilization rate of patents and promotes commercialization of outcomes from commissioned R&D projects. This delegation hopes that its information helps other delegations create their own domestic policies. And this delegation looks forward to hearing your active inputs on this agenda item.

### **11.13 Mexico**

356. Mexico would like to thank Australia, Canada, Chile, Hong Kong, Japan, Korea, New Zealand, Singapore, Switzerland, Chinese Taipei and the United States for proposing that this item be included on the agenda of the meeting; we also thank the other speakers who have already taken the floor.

357. Innovation is currently one of the most important issues in the field of intellectual property. The Mexican Industrial Property Institute (IMPI) promotes innovation, while also ensuring the protection of inventions and trademarks.

358. In May 2010, Mexico created the Sectoral Innovation Fund (FINNOVA), which is administered by the Ministry of the Economy and the National Science and Technology Council (CONACYT).

359. FINNOVA's objective is to promote innovation in the country through mechanisms that help to convert ideas into business projects (business incubators), and to foster the linkage between universities, research centres and companies.

360. Through FINNOVA, the Ministry of the Economy and CONACYT, in partnership with IMPI, have developed a systemic strategy to enhance the protection and exploitation of innovation. This strategy includes the strengthening of patenting centres (CePat).

361. A patenting centre is an office that carries out activities relating to intellectual property rights management. Such activities range from identifying projects eligible for protection, providing advice on conducting prior art searches, and preparing patent applications for inventors (industrial property), authors (copyright) and breeders (plant varieties), to providing support for completing the necessary formalities before the relevant authorities. All of this is done to increase the number of national patent applications, the commercialization of patents granted through the licensing of rights and the transfer of technology, as well as to help build an industrial property portfolio. The main activities of patenting centres also include the organization of intellectual property-related promotional events, workshops, courses and seminars, the training and updating of human resources, and the preparation of promotional materials.

362. Patenting centres have been promoted by IMPI with a view to building the capacities needed to develop the country's patent system and to enhancing the tools and skills required by research centres to better protect their intellectual property.

363. In recent years, new patenting centres have been set up throughout the Republic. There are currently 106 centres in Mexico (46 of which are operational and 60 of which are at the start up stage).

364. In 2018, patenting centres filed 341 patent applications and 285 trademark applications and were granted 106 patents and 223 trademark registrations.

### **11.14 European Union**

365. The EU would like to thank the United States and Singapore for introducing the two respective papers for this agenda point to which we are a co-sponsor.

366. Intellectual property rights are the main commercialisation tool of R&D activities and can be seen as the value R&D creates. The commercialisation of R&D is fundamental in creating economic growth. Two-thirds of economic growth in Europe from 1995 to 2007 derived from R&D.

367. The main umbrella programme enabling public-private research collaboration in the EU aiming at leveraging R&D is the Horizon 2020 programme. Horizon 2020 is delivering scientific impacts through the reinforcement of research and innovation capabilities, scientific excellence and through the integration of research and innovation with as well as supporting private sector participants in their efforts in commercialisation. Horizon 2020 projects have the potential to generate a large number of scientific breakthroughs; researchers have already contributed to major discoveries like exoplanets, the Higgs boson and gravitational waves. At least 17 Nobel Prize research got support from Horizon 2020 prior or after the award.

368. Horizon 2020 builds cross-sectoral, inter-disciplinary, intra- and extra-European networks. The Horizon 2020 programme is successful in attracting and involving the private sector (33.2%), a necessary precondition for the achievement of innovation and economic impact. In particular, Horizon 2020 attracts and involves many SMEs, the backbone of the European economy. Horizon 2020 is creating networks between businesses, and between the business sector, universities and research institutions, also allowing them to make better use of the IP system, which is of huge importance to bringing knowledge quickly to market. Horizon 2020 provides companies, and in particular SMEs, with access to risk finance to carry out their innovation projects. 5,700 organisations have been funded under the Access to Risk Finance programme part (EUR 13 billion of private funds leveraged; EUR 29.6 billion of investments mobilised via debt financing); numerous SMEs are taking part in the SME Instrument until end-2016 secured a total of EUR 481 million of venture capital during or after the project, also with the intellectual property rights they developed.

369. Horizon 2020 generates large numbers of high quality, commercially valuable patents and other intellectual property rights, so far mainly from the SME Instrument. Horizon 2020 also generates proofs of concept and demonstrators and supports the deployment of innovative solutions supporting the commercialisation and diffusion of innovation, including hundreds of prototypes and testing activities, as well as numerous clinical trials.

370. Horizon 2020 projects produce new knowledge, strengthen capabilities, and generate a wide range of innovation outputs including new technologies, products, services and the related intellectual rights: 563 firms have been introducing innovations new to the market (56% SMEs) and more than half of SME Instrument Phase 2 beneficiaries have already reached the market.

371. Every euro invested under Horizon 2020 brings an estimated GDP increase of EUR 6 to 8.5. This means EUR 400 to EUR 600 billion by 2030.

372. Many of the Horizon 2020 supported projects demonstrate potential in terms of generating breakthrough, market creating innovation. A quarter of the ongoing Innovation Actions are regarded as having breakthrough, market creating potential. Let me therefore finish with two concrete examples that show the positive global impact of the Horizon 2020 programmes also beyond Europe:

373. The first Horizon 2020 project is producing bioethanol from steelmaking process emissions. The project STEELANOL demonstrates the industrial production of bioethanol from emissions of the steelmaking process, which has the potential to significantly reduce greenhouse gas emissions compared to oil-derived fuels. A demonstration plant of approximately 25,000 tons/ethanol per year will be built in Belgium; the largest facility built to date utilizing this technology globally. This high-risk/high-impact project is expected to contribute to achieving the targets of the Paris Agreement on climate and advancing the circular economy.

374. The second project is on public-private partnership in the pharma sector. The outbreak of Ebola in West Africa was one of the international health emergencies of the past few years. EUR 24.4 million from Horizon 2020 were urgently mobilised. In parallel, the IMI-Ebola+ public-private partnership call was launched in record time. This Horizon 2020 research response, very significant in scale, with a total of EUR 140 million, in turn, leveraged a further EUR 101 million from the pharmaceutical industry. Without the possibility to use IP, such additional private funds would have been very unlikely to have been mobilised. These joint efforts are already delivering, with trials on the ground in West Africa and with the first indication of results.

375. We therefore would like to conclude that in the EU public-private partnerships in R&D play a fundamental role in support of innovation and allowing the development of intellectual property rights, ultimately necessary for the successful commercialisation of private innovation. Only when all forces, public and private alike, are mobilised, can we fully leverage the global innovation capacities needed for the desired outcome of economic development and the tackling of our joint global challenges.

#### **11.15 Korea, Republic of**

376. As a co-sponsor of the agenda item on IP & Innovation, Korea would like to join previous speakers in emphasizing the importance of the private and public collaboration in promoting IP, particularly R&D. The value of Private and Public Partnership is bigger for the small and medium size enterprises, which often lack the necessary capital and know-how in building IP. Recognizing this, Korean government has been carrying out various projects in collaboration with the private sector to help SMEs establish and promote IP.

377. Korea Intellectual Property Office (KIPO) provides SMES with various training opportunities that will help them build IP in cooperation with business associations. Through these opportunities, entrepreneurs or executive managers of those SMEs could learn how to better carry out R&D, and how to commercialize their IPs in the real market.

378. Close partnership between business and academia has been promoted as well by government-initiated projects. KIPO has been providing a platform for collaboration between prestigious tech colleges and SMEs and supporting for innovative ideas brought up by tech colleges to serve as valuable input for R&D projects of SMEs.

379. Public-private partnership has a crucial role to play in maximizing the potential of developing IPs and in further promoting innovation and creativity. In this sense, Korea hopes that Members of the Council will continue to share their national experiences of promoting IPs through close cooperation between public sector and private sector under this agenda item throughout 2019.

#### **11.16 Brazil**

380. We would like to thank the co-sponsors for presenting the topic "Public-Private collaborations in Innovation" under the item on IP and Innovation.

381. Brazil's new administration has a clear vision of the key role IP can play in the economy and important strides will be made to improve our IP institutional framework so as to further increase the level of innovation of our economy.

382. In our view, innovation is the main driver of a country's competitiveness and economic growth in the medium-long term.

383. IPRs help create conditions that permit and encourage individuals and businesses to experiment new approaches and solutions, which benefit society as a whole.

384. The idea of advancing knowledge and technology has been recognized from the start as a core goal of the intellectual property system. Indeed, the TRIPS Agreement, in its preamble, recognizes "the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives".

385. In order to be sustainable, however, we have to ensure that the fruits of human ingenuity are enjoyed as widely as possible worldwide while preserving proper incentives and rewards for innovators and creators. This is of utmost importance to the credibility and legitimacy of the IP system.

386. Brazil welcomes the issue of public-private collaborations in innovation. We believe there are a number of important dimensions to explore in this topic. We are convinced these type of collaborations contribute to boost R&D expenditures.

387. The latest data available, provided by the World Bank, shows that R&D expenditure in Brazil as proportion of GDP reached 1.28% in 2015, by far the highest amount in Latin America, and higher than several OECD countries.

388. Notwithstanding the fact that the levels of R&D spending are an important proxy to innovation, we know they are not synonymous. Given our levels of R&D expenditures, we should be a much more innovative economy. As we all know, however, an ecosystem that fosters innovation depends on a variety of factors.

389. Our new administration intends to put in place a number of structural reforms that will not only improve the business environment in Brazil but will also deeply integrate the country in the world economy. As a result, Brazil expects to develop a much more effective IP system to convert innovation and creativity into tradable commercial assets.

390. We believe a closer, balanced and fine-tuned partnership between the public and private sector can contribute to create such an outcome. Brazil has been implementing a number of measures to strengthen this collaboration to develop a dynamic and innovative ecosystem.

391. Brazil's IP office has established a broad array of partnerships with different institutions, public and private, that are part of the Brazilian innovation system: National Confederation of Industry, Brazilian Development Bank (BNDES), the Brazilian Trade and Investment Promotion Agency (Apex), the Micro and Small Business Support Service (SEBRAE), the Brazilian Industrial Development Agency (ABDI), the Brazilian Agency for Industrial Research and Innovation (EMBRAPII), the antitrust agency (CADE), the Association of Brazilian Technological Parks, and with some world class Brazilian universities, among others.

392. These partnerships will benefit from the recently approved New Innovation Law (Law nº 13.243/2016 and Decree nº 9.283/2018). One of main goals of the new Law is to stimulate the cooperation and interaction between public and private sectors; to boost innovation in companies and science and technology institutions (STIs); and, mainly, to simplify procedures for the management of science, technology and innovation projects and the adoption of performance monitoring.

393. The New Legal Framework has broadened significantly SEBRAE's scope of action to support innovation. For those not familiar with SEBRAE, our Micro and Small Business Support Service, it plays a major role in articulating and promoting small business access to innovation and technological services. SEBRAE invests at least 20% of its annual budget in innovation and technology.

394. Another example of a successful partnership is the agreement signed between SEBRAE and our IP office, which created a fast track for the analysis of pending patent applications for SMES. 36% of all small businesses that have used the programme have already had their patents granted.

395. Another success story in promoting IP and innovation in Brazil is EMBRAPII, the Brazilian Agency for Industrial Research and Innovation, a Social Organization connected to the Ministry of Science, Technology, Innovations and Communications (MCTIC) and to the Ministry of Education (MEC). The agency finances innovation projects in partnership with research centres (EMBRAPII Units) to increase competitiveness of the productive sector. Brazil has 42 EMBRAPII Research Centers spread around the country. EMBRAPII has already supported 650 projects, 460 companies and technologies developed have generated 140 patent applications (42% of medium enterprises, 41% of micro and small e 17% of big companies). These patents were filed in the field of advanced manufacturing, biotechnology, chemistry and IoT technologies.

396. Some examples of projects developed by EMBRAPII:

- Smarter city manager - the innovation, developed by the EMBRAPII Intel Unit and the Ericsson company, integrates different areas of interest of public agents, such as Public Safety, Intelligent Transportation Systems, Intelligent Lighting, in a single platform. This integration allows efficiency gains, faster responses and improves the quality of services provided to the community.

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- Nanoencapsulation technology - Four large competing companies, Boticário, Yamá, TheraSkin Farmacêutica and Natura, joined EMBRAPII Unit to share the production of a new nanoencapsulation technique. The innovation allows active principles to be delivered to the innermost layers of the skin, where products such as creams or ointments cannot reach.
- Vegetal Biostimulants-Biofertilizers produced from macroalgae and cyanobacteria extract from the Brazilian biodiversity using 100% national technology. The project, developed by the EMBRAPI Agroenergy Unit and the Dimiagro company, will bring more productivity to the crops and savings to producers.

397. On the issue of public funds and commercialization of IP, EMBRAPII and SEBRAE have developed the *Disruptive innovation Fund in 2017*: the programme is intended to bridge the gap between SMEs, large companies and Science, Technology and Innovation (STI) Institutes. In this model, 1/3 of every project receives EMBRAPII resources, up to 1/3 from EMBRAPII-accredited Technological Institutes and the rest from participating companies. SEBRAE subsidizes up to 80% of the small company's contribution to the project. Through this agreement, small companies have access to top laboratories and researchers in the country. Four innovation funding programmes have been launched so far, reaching companies from 20 different technological areas in 19 Brazilian states. Up to October 2018, SEBRAE committed USD 3 million in projects of 74 companies, which were leveraged up 4.2 times, amounting to USD 13.5 million.

398. Universities still play an important role in the development of innovation in Brazil, thus we would like to mention the case of UNICAMP, a public university from the state of Sao Paulo. Some relevant data about UNICAMP:

- Number one Brazilian university in number of patents;
- Second position in the Latin America´s top ten universities rank (the first one the Brazilian USP);
- Ninth position among BRIC universities.

399. UNICAMP has its own Technology Transfer Office (TTO), which is called INOVA UNICAMP. Inova promotes interaction between the University and companies through the offer and the licensing of technologies developed at UNICAMP and the negotiation and monitoring of collaborative research contracts. The university interacts with companies of all sizes. Innovative small companies can benefit from the proximity to the university in collaborative projects and by being incubated at INCAMP, UNICAMP's Technology Based Incubator. Medium and large companies rely on Inova to assist them in identifying new technologies and research groups for technological development partnerships and have the option of being hosted in an innovation laboratory within UNICAMP's Science and Technology Park.

400. Inova UNICAMP in numbers (2017):

- Over 100 licensed technologies; Annual income of more than USD 325.000;
- Over 70 partner companies;
- Average of 70 patents filed per year in Brazil; 81 patent applications filed in 2017;
- 485 UNICAMP-born companies active in the market with revenue of USD 750 million, generating more than 28.000 direct jobs.

401. Some examples of licensed technologies in 2018:

- Sugar-cane productivity monitoring system (patent number BR0502658-0; UNICAMP/Agricef) – the system is attached to harvesters and enables collection of productivity data. The data is used for productivity maps and production management. The

monitoring system uses load cells and sensors, such as accelerometers and GPS, which communicate with the on-board computer of the harvester via a CAN network.

- Facial analysis method for device control (BR 102016027065; PCT/BR2017/000136; BR5120160013729; UNICAMP/Hoobox Robotics) – Using face analysis, the system translates commands and controls electronic and mechanical devices. The technology, implemented in wheelchair by the licensed company, works like a 3D camera that captures expressions, classifies them and carries out the desired command.
- Unique identity method in virtual environments (patent number BR 1020120057956) – Method developed in partnership between UNICAMP and Kryptus, licensed in 2012, that creates a unique identity for each computing device in which it is implemented, providing more security for user data and information. The technology is being used in the financial sector, with application in virtual environments such as internet banking.
- Microencapsulated crystals as an alternative to trans-fat (patent number BR 1020140279997; Noviga/Unicamp) – a method to nanoencapsulate trans-free fat crystals, which are similar in terms of structure, consistency, appearance and taste to trans-fat products. The technology provides a possible substitute to trans-fat in the food industry, without harm to consumer health. The new process is advantageous in terms of logistics, costs and final product stability.

402. Brazil remains deeply committed to encouraging, rewarding and disseminating innovation in the economy and society through public-private partnerships.

403. These are some of the examples we chose to share with you. We hope we have the opportunity to learn from other Members' experiences as well.

#### **11.17 China**

404. China thanks Members to add this item into agenda and submit these documents. In 2018, the Societal Values of IP in New Economics has been discussed and positive results have been achieved. China also joined the discussion and shared our practices.

405. China pays great attention on the important role of innovation and IP protection in new economies. In order to encourage innovation and creativity, on one hand, the legal system of IP protection has been improved. Based on Patent Law, Trademark Law and Copyright Law, China has set up modern regulation and law system on IP protection. Currently, China is working on amending the Patent Law and the Copyright Law. Besides, China continuously strengthens law enforcement on IPR protection. China has set up three IPR courts in Beijing, Shanghai and Guangzhou, and special judicial organs at 15 intermediate courts in Nanjing, Suzhou and other cities to handle cross-regional IPR cases, including those related to patents. China has also strengthened administrative enforcement and launched special campaigns.

406. China has taken great efforts and made great achievements on IP protection and innovation promotion. In 2017, China received 1.382 million invention patent applications, ranking the first in the world for the seventh consecutive year. Nearly 10% of the applicants were foreign entities and individuals. Invention patent applications filed by foreign entities and individuals in China reached 136,000. According to the World Intellectual Property Organization, 51,000 patent applications filed from China through the Patent Cooperation Treaty were accepted in 2017, second only to the US. Besides, new technologies are also in the fields as high-speed trains, nuclear energy, new generation telecommunication, aerospace and etc.

407. Meanwhile, it should be noted that most of the Patents in China are patents for utility models and design patents, patents for invention are not as much as others. According to the statistics by World Bank, China collected USD 4.7 billion patent fees, amount to 1.3% of world total, while paid USD 28.6 billion patent fees, with USD 23.8 billion deficit.

408. Therefore, China hopes to draw Member's attention to the following facts. Firstly, it is agreed that for generation and development of new business, besides innovation and IPR protection, capital, human resources and other elements are also essential, for developing Members, capital and human

resources play an even more important role. Secondly, innovation cannot be achieved in one day. It needs huge amount of investment and primitive accumulation. Compared to the developed country Members, developing country Members suffer deficiency in primitive accumulation. Currently, there still exists wide gap between developed and developing country Members on the level and ability of innovation. We hope that Members can realize this and explore effective solutions.

### **11.18 India**

409. India would like to reiterate its statements on this issue made in earlier meeting. India is of the view that while IPRs may provide an incentive to innovate, they are neither necessary nor a sufficient condition and could only be effective in certain contexts.

410. Though, India realizes importance of innovation and keeping that in view, India has taken many steps to improve the innovation eco system-whether it is through the quality of the human resource or the research and development activities or strengthening of academia industry linkages and availability of capital. As a result, India has moved up on the Global Innovation Index from a rank of 76 in 2014 to 57 in 2018. During the same period India has made substantial progress in improving its ease of doing business ranking, reaching to rank of 77 out of 190 countries surveyed, making it the only country to rank among the top ten improvers for the second consecutive year. Since 2014, India's ranking improved 65 places from 142nd in 2014 to 77th in 2018.

### **11.19 Dominican Republic**

411. By means of Decree No. 453-18, the President of the Dominican Republic, Danilo Medina, has declared 2019 as the Year of Innovation and Competitiveness. Similarly, in January 2019, the Roundtable on Competitiveness, which is chaired by the honourable President of the Republic and which brings together the country's leading entrepreneurs, discussed the need to develop a strategy and schedule for the formation of public-private partnerships for innovation in the country. In this regard, my country is very interested in seeing what WTO Members can offer in terms of support and technical cooperation, and we request that the submissions made today under this agenda item be circulated.

## **12 INTELLECTUAL PROPERTY AND THE PUBLIC INTEREST: PROMOTING PUBLIC HEALTH THROUGH COMPETITION LAW AND POLICY**

### **12.1 South Africa**

412. South Africa wishes to continue the discussion on the linkage between intellectual property and competition law and policy based on the documents which are contained in the circulated document IP/C/651, which includes *inter alia* IP/C/643; IP/C/W/649 and Addenda.

413. We wish to continue this debate with specific reference to exploitative excessive pricing and restrictive practices such as reverse payment agreements, strategic patenting and more lately, the evolution of niche pricing of off-patent pharmaceuticals.

414. The discussion has gone through various phases of debate, based on underlying guiding questions. During the TRIPS Council meeting of 5 and 6 June 2018, co-sponsors endeavoured to enhance the understanding of Members of the various approaches to competition law and policy and how competition norms are used to prevent or deter practices such as collusive pricing or the use of abusive clauses in licensing agreement that unreasonably restrict access to new technology and prevent the entry of generic companies and may result in higher prices for medicine.

415. We specifically pointed out that while the TRIPS Agreement sets "minimum norms" for standards of IP protection that significantly limit Members' discretion on a large number of IP rights issues, it is however not the case with competition law.

416. During the TRIPS Council meeting of 8 and 9 November 2018, we intensified the debate by pointing out that over the course of time clearer competition policy treatment of IPRs has evolved through either iterative processes or the evolving practice of competition authorities. This development, as we argued, underscored the need for further debate and analysis since competition law and policy is no longer the preoccupation of only a few jurisdictions.

417. A recent publication of the European Commission entitled "Competition Enforcement in the Pharmaceutical Sector (2009 – 2017)" sheds light on the efforts of European competition authorities to ensure affordable and innovative medicine.<sup>10</sup> It should be noted that not all jurisdictions prohibit exploitative excessive pricing, however excessive pricing models may often be indicators of underlying competition problems. Unlike the binding minimum standards of intellectual property protection and enforcement contained in the TRIPS Agreement, there is no equivalent international legal instrument for competition law that would provide such minimum standards of protection.

418. Competition policy has an important role to play in ensuring fair access to medical technology and fostering innovation in the pharmaceutical sector. WTO Members have absolute policy space under international law to design their national competition laws in accordance with their domestic interests and needs and the level of their development.

419. We want once again to urge Members to share their national experiences and examples of how competition law is used to achieve public health and related national objectives. Debate and information exchange could serve to enhance the understanding of Members of various approaches to the use of competition law and policy to prevent or deter practices such as: collusive pricing or the use of abusive clauses in licensing agreements that unreasonably restrict access to new technology, the use of measures that prevent the entry of generic companies and result in higher prices for medicines, reverse payment agreements and strategic patenting, patent thickets and product switching.

420. We also focus on capacity building and technical assistance which remains an important means to enable WTO Members to increase their capacity to administer and implement policies that ensure access to medicines within the TRIPS flexibilities framework.

421. We also have a list of questions circulated in document IP/C/W/651. I will focus in questions 4 and 5 only:

(4) Have any Members recently conducted market inquiries into the pharmaceutical sector to assess its impact on access to medicine or more generally the impact of the pharmaceutical sector on competition in particular market segments? If so, what were the findings and what remedial actions were recommended or taken?

(5) To what extent can technical assistance and capacity building contribute to the delivery of more effective policies by WTO Members in the field of competition law to address the abuse of intellectual property rights? What role can international organisations play in this regard, including the WTO?

## **12.2 Costa Rica**

422. Thanks to South Africa for its communication and for introducing this topic in the agenda. As a means to contributing to this debate, Costa Rica would like to briefly refer to some of its experience in this area.

423. When dealing with excessive pricing in the context of anti-trust or competition enforcement in the pharmaceutical and medical technology sector, our competition legislation does not contemplate specific provisions to deal with these sectors, but pharmaceutical and medical technology goods fall within the scope of our competition law. If there is proof that lack of competition in a particular sector might have as a consequence high prices, temporary price regulation might be implemented as a remedy to deal with these cases.

424. The Ministry of Economy and Industry of Costa Rica is currently leading a market study to analyse the impact of possible monopolistic practices on the most sold pharmaceutical products in the country. The results of this study are still pending and will be made publicly available in due time.

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<sup>10</sup> European Commission "Competition Enforcement in the Pharmaceutical Sector (2009 – 2017)" European Competition Authorities working together for affordable and innovative medicine. (dated 28 January 2019). <http://ec.europa.eu/competition/publications/reports/kd0718081enn.pdf>

425. Finally, with respect to technical assistance and capacity building needed to deliver more effective policies by WTO Members in the field of competition law, Costa Rica believes that in the specific case of pharmaceutical products, it would be helpful to have technical assistance both from the WTO and entities related to the field of public health such as the WHO and the PHO in a coordinated way, in order to reach an appropriate balance between IPR protection, trade and public health.

### **12.3 Brazil**

426. Brazil would like to thank the co-sponsors for including in the agenda the important topic of "promoting public health through competition law and policy" under the item IP and the Public Interest.

427. The promotion of competition and the protection of IPRs are essential cornerstones for the development of a modern economy, and the challenge Members face, irrespective of their level of development, is to find the right balance between both policies.

428. In a well-functioning market economy, IPRs may provide incentives for competition, based on the promise to grant exclusive rights to products or services that eventually bring a benefit to society and, as a result, more competition in the medium-long term. For this incentive mechanism to function, however, it is essential that existing IPRs not be employed abusively, harming competition and innovation in the short term at the expense of IP users.

429. In this sense, competition laws play a key role in ensuring that the exercise of exclusive intellectual property rights do not give rise to anti-competitive practices, whether through the abuse of the IP holders' dominant position in the market or unlawful agreements among right holders themselves.

430. On patents and health, we believe innovation, bolstered by the patent system, has produced a number of important technologies that have improved health outcomes worldwide. Innovation is also vital to achieving the 2030 Agenda's goal of improving the health and well-being of all people at all ages, which appears in a number of SDG targets.

431. While important progress has been made, significant gaps persist in health, innovation and access. To mention one example, according to WHO and the World Bank, 400 million people worldwide lack healthcare, including access to medicines, vaccines and medical devices. Three quarters of them live in middle-income countries. Furthermore, an estimated 1.7 billion people in 185 countries still need treatment and care for neglected tropical diseases.

432. The WTO, WIPO and WHO report on IP and Public Health highlights that: "Several potentially anti-competitive strategies in relation to IP rights involving medical technology have been observed and documented. These strategies mostly are designed to extend patent protection for originator drugs and to prevent market entry by generic competitors after patent expiry."

433. The UNDP report, entitled "Using Competition Law to Promote Access to Health Technologies", also provides a thorough analysis of different strategies companies use to try to curb competition. The same document underlines the importance of competition law as one of the important tools to promote innovation and access to health technologies.

434. In our view, the use of competition law to curb abusive conduct is in line with both the letter and the spirit of Article 7 of TRIPS, which states that: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

435. Article 8.1 of the TRIPS Agreement also recognizes that the principles of IP protection are based on underlying public policy objectives.

436. Various other provisions of TRIPS are relevant to competition law including Article 6, Article 31(k) and Article 40. These provisions leave broad discretion to Members in how they apply competition law in respect of the acquisition and exercise of IP rights.

437. We would like to highlight that Brazil's approach to IP and Competition aims to be cautious, balanced and pragmatic.

438. The Administrative Council for Economic Defense (CADE) is the Brazilian Antitrust Authority responsible for applying Law 12.529/2011 (Antitrust Law). The institutional dialogue between CADE and our IP office (INPI) has been intensified through a recent agreement for the exchange of knowledge, information and technical cooperation. The objective of this increasing collaboration is to ensure IP and antitrust laws are equally respected and assessments are made on a case-by-case basis.

439. Based on this cooperation, CADE found Eli Lilly of Brazil and Eli Lilly and Company guilty of sham litigation in order to obtain exclusive marketing rights (EMR) for a medical drug used in cancer treatment in 2015.

440. In our view, such intra-agency dialogue and cooperation ensures stability, reliability and legal certainty, essential elements of a conducive business environment and for attracting investment and innovation.

441. Pursuing a better alignment between IP, trade and health policies is an ongoing, never-ending process. That's why, we, Members, have to continue working together to develop a balanced and effective international patent system that encourages and rewards innovation and, at the same time, is supportive of public policy objectives.

442. That is why we believe the item "IP and Public Interest" is of utmost importance and should be further explored in the TRIPS Council agenda in future sessions.

443. In the Eli Lilly Case, the Brazilian Association of Generic Medication Industries filed a complaint against Eli Lilly of Brazil and Eli Lilly and Company, alleging that the defendants had practiced sham litigation by unlawfully enforcing patents in the medical drug market. The plaintiff claimed that the defendants were creating artificial barriers to competition by filing suits against public institutions, such as the INPI, in order to obtain unlawful exclusivity over a medical drug used in cancer treatment. CADE's ruling identified an abuse of IP rights in Eli Lilly's conduct. According to CADE, the claims filed by the defendants fulfilled the three requirements for establishing sham litigation, as developed by case law: (1) implausibility of the claims, (2) provision of erroneous information and (3) unreasonableness of the means used. The agency highlighted the importance of careful scrutiny in sham litigation cases involving IP rights due to the high potential of such cases to cause very harmful effects on competition. CADE addressed the complex interface of antitrust and IP law, noting that even patents lawfully granted by the designated government agencies did not preclude the possibility that these IP rights could be abused in enforcement proceedings.

444. CADE found the defendants guilty of sham litigation for the following reasons: (i) the suits filed by Eli Lilly were manifestly unreasonable in the sense that they were not credible and had no chance of succeeding, since the patentability of the pharmaceutical product whose IP was being enforced had never been analysed by INPI; (ii) the defendants omitted relevant information, such as the suspension of the patent review and the modification of the patent scope, from their submissions filed in the judicial suits; and (iii) the means used to enforce the IP rights were deemed unreasonable since the same claim had been filed in several different courts. The defendants had obtained an unlawful monopoly, harming competition, by filing various judicial claims to avoid the practical effects of the refusal to grant the requested patent in order to obtain EMR.

445. This ruling exemplifies an instance where CADE applied antitrust rules in a case involving the abuse of IP rights. The defendants' conduct in the Eli Lilly case had clearly been abusive and the resulting unlawful monopoly had caused serious harm to competition.

## 12.4 Indonesia

446. Firstly, we would like to thank South Africa for registering this agenda item for this TRIPS Council meeting. There are many ways for us to achieve and promote public health objectives for the good of public interest and one of those ways is through competition law. In this opportunity, Indonesia would like to share its experience related to the topic of this agenda item.

447. Indonesia enacted a law in 1999 which prohibits monopolistic practices and unfair business competition among business actors. Within that law, there is a mandate for Indonesia to establish an agency to implement provisions within the anti-monopoly law. The Indonesian Anti-Monopoly Agency was established in 1999 and since its kick-off in the year of 2000 until 2017 it has handled 348 cases including collecting fines of up to IDR 2.07 trillion.

448. Based on Article 50 letter (b) of the anti-monopoly law, there is an exception concerning exclusive rights of intellectual property rights (IPRs). However, the exclusivity of IPRs cannot be considered unlimited. Based on the anti-monopoly law, if monopolistic practices and unfair business competition are found through the use IPRs, the agency has an obligation make corrections.

449. In 2010, there was a case which was handled by the agency, Case Number 17/KPPU-I/2010 concerning Prohibition of Monopolistic Practices and Unfair Business Competition Law on Am-lo-di-pine Therapy Class Pharmaceutical Industry. This case contained issues on the dominant position of cartels in determining prices for certain medicines. Within its finding, the agency determined that the exclusivity of IPRs cannot be classified as a license agreement but rather as a supply agreement.

450. In the health industry of a country of about 260 million people, "pricing abuse" often occurs in the pharmaceutical sector, where the price of drugs and medicine tends to be very high. It happens because drugs are considered as inelastic goods, where prices and demand do not affect each other. Such conditions created a notion in Indonesia that the price of drugs must be controlled to prevent further abuses and most importantly to protect consumers and the public interest.

451. Hence the Indonesian Government created a regulation related to drug pricing which guides the upper limit price for certain medicines. In addition to that, an electronic catalogue on drugs and medicines, which is used as a tool to support the National Health Insurance System, was also introduced. Since the introduction of this initiative, there is a tendency for drugs and medicine prices to decrease in Indonesia.

452. This is an example on how the anti-monopoly law is used in Indonesia to ensure public interest. We look forward to hearing other Members' experiences on this subject matter.

## 12.5 China

453. In 2018, Members are actively involved in the discussion of intellectual property and the public interest, the understanding of this issue has been deepened. In the third meeting, the relationship between IP and competition were discussed from the viewpoint of anti-unjustified competition, although divergences still exist, the discussion were open and inclusive. China believes that our discussion today will further the understanding of this relationship.

454. China reaffirms that TRIPS Council is an appropriate forum to discuss IP and competition issues. China believes the discussion will help Members to get a better understanding of this issue.

455. In our point of view, firstly we believe that intellectual property protection should not exclude the application of competition law. Articles 6, 8.1, 31(k) and 40 of the TRIPS Agreement are closely related to competition. Actually, In WIPO and FTAs, this issue already has been discussed a lot. As an important forum for intellectual property, the TRIPS Council should discuss this issue as well.

456. Secondly, China conducts investigation and law enforcement on monopoly issues in the field of medicine, including IP abuse excluding competition and others. In 2017, Guidelines for Operator's Pricing on Deficient Medicine and Drug Materials was introduced for this purpose.

457. Finally, China emphasizes the discussion of IP and competition should be open, Members can exchange views and experiences on the flexibility articles in TRIPS including better understanding of competition laws based on their own legislations and practices.

## **12.6 Switzerland**

458. I thank the distinguished delegate of South Africa for introducing its submission IP/C/W/651. Competition law opens a broad and challenging field. To a large extent, this field is outside of the responsibility of the TRIPS Council.

459. The goal of the IP system is to grant a time limited exclusive right for the use of intellectual property to its owner. The IP system addresses and remedies an economic market failure to ensure sufficient incentive for investment into and for the promotion of innovation and dissemination of innovative technology.

460. An IP right may provide one of many possible backgrounds on which anti-competitive behaviour or an abuse of market power may occur. Competition and anti-trust law are, however, concerned with that anti-competitive behaviour as such - and not with the underlying IPR.

461. It is, therefore, misleading, in our view, to refer to competition law as a TRIPS flexibility. Competition law is not to make inroads or provide exceptions to IPR or to their protection as stipulated in the TRIPS Agreement.

462. There is no direct or necessary link between IP and price either, be it in the pharmaceutical or any other sector. A patent does not grant the right to demand a specific price, not to mention excessive ones. This is illustrated by the fact that excessive pricing, whether in the pharmaceutical or other sectors, may occur regardless of whether respective products are patent protected or not. It's practices such as collusive pricing or abusive clauses in licensing agreement that are the subject-matter of examination by competition law - and not IPRs.

463. How competition law shall address such anti-competitive behaviour is, in this delegation's view, outside the purview of the TRIPS Council and not its field of competence.

## **12.7 United States of America**

464. The United States has provided its views on this agenda item during the two previous TRIPS Council meetings and references, but will not otherwise repeat, its June 2018 intervention on this agenda item.

465. The United States continues to be of the view that intellectual property laws and antitrust laws share the common purpose of promoting innovation and enhancing consumer welfare, but also that intellectual property and competition are distinct disciplines implemented and overseen by different administrative authorities.

466. The United States continues to express reservations regarding discussion of this subject matter in this forum, as relatively few TRIPS Council delegates can be expected to have deep expertise both in intellectual property and competition law and policy.

467. We note that there are already established forums, including the Organization for Economic Cooperation and Development (OECD) and the International Competition Network (ICN), which bring together the appropriate experts to discuss such issues.

468. As we have demonstrated in the United States, IP and competition polices can and should coexist and complement one another.

469. The United States is committed to achieving public health goals in a way that upholds IP rights and promotes competition.

470. For more information on the United States' views on IP and competition, please refer to our June 2018 intervention.

## 12.8 Japan

471. For the purpose of having meaningful discussions under this agenda item, the delegation of Japan would like to suggest other Members to note that it might be better to take a more thorough and cautious approach, taking into account not only the interests of third parties but also those of patent-rights holders.

472. We all should note that the development of new and innovative medical technologies needs so much cost and takes so much time as well, and therefore Japan believes that there should be an appropriate mechanism to incentivize the development of such technologies not only for the developed country Members but also for the whole world.

473. Taking the above-mentioned points into account, we believe the IP system is an essential mechanism that should work without undue barriers to promote dynamic competition. In particular, the current IP system plays a significant role to incentivize the development of new and innovative medical technologies for several purposes, such as to overcome incurable diseases and to lower the cost of production of existing medicines.

474. In this context, this delegation would also like to point out that provisions such as those in Article 31(k) and Article 40 of the TRIPS Agreement, which refer to the relationship between IP and competition policy, rest on an intricate balance. Therefore, Japan believes that we should be cautious, in discussing this agenda item. And, these provisions should not be interpreted too broadly. From this perspective, this delegation has concerns about the document IP/C/W/651. In addition, it is important to note that any measures taken under these provisions should be fully consistent with the TRIPS Agreement, as is stipulated in Article 8 or Article 40.2 of the TRIPS Agreement.

## 12.9 European Union

475. Competition law and intellectual property systems are not contradictory, but complementary systems of law, which both strive to further welfare and growth. As already stated at the last two TRIPS Council sessions, in general, we do not consider the TRIPS Council the appropriate forum to discuss competition policy. There are other international fora, such as the International Competition Network, where such international exchanges and cooperation are taking place and we invite all WTO Members' competition authorities to participate in those fora.

476. While the submission from South Africa seems to consider the use of competition policy a TRIPS flexibility to facilitate the market entry of generic competitors, the EU would be cautious and would emphasise the following: while the TRIPS agreement is obviously compatible with the application of competition policy measures, it clearly does not allow for "absolute policy space". As provided for in Article 8 (1) and (2), as well as in Article 40 (2), these measures have to be consistent with the provisions of the TRIPS agreement and cannot be used as tools in avoiding the obligations under the Agreement.

477. Generally, of course, competition policy plays an important role in controlling and sanctioning anti-competitive market behaviour in any sector, including the pharmaceutical sector.

478. However, competition authorities in the EU have been generally reticent to address possible excessive pricing conduct. In a market economy, prices and profits are generally regarded as useful indicators and necessary incentives for other firms to decide where to invest, enter a certain market or expand their business. Lastly, if high profits are the result of a firm's own excellence and innovativeness, the incentive for such efforts should not be undermined by ex-post competition policy enforcement. While these reasons, which justify a cautious policy, are generally well understood, Treaty on the Functioning of the European Union (TFEU) Article 102 has an explicit abuse prohibition of excessive pricing, which has been further developed by the European Court of Justice.

479. However, in the EU, there were no competition cases of excessive prices related to intellectual property rights. EU authorities, including the Commission, have so far intervened in cases where, due to market failure, older, off-patent drugs saw their prices increase by up to over 2000%. In these cases, i.e. drugs which were no longer protected by intellectual property rights, high prices were not related to intellectual property rights and did not act as an incentive for innovation, which

intellectual property rights aim at safeguarding. Conversely, the European Commission has never reached the conclusion that the pricing of an innovative medicine was excessive.

480. Moreover, competition enforcement should not only safeguard static price competition, but also be mindful of the need to secure dynamic competition for the development of new, innovative drugs. Both the Commission's recent Report on Competition Enforcement in the Pharmaceutical Sector as well as the Commission's Sector Inquiry recognize the value that systemic protection of intellectual property rights, together with the other incentives on the pharmaceutical markets (e.g. incentives for development of orphan medicines), bring by stimulating innovation and increasing choice for the patients. They also recognize that many legitimate practices of pharmaceutical companies rely on the intellectual property framework (e.g. patent strategies, patent litigations and settlements, patent oppositions).

481. Abusive conduct of pharmaceutical companies, as any other abusive practices, can violate competition law in certain clearly defined circumstances, and provided that all applicable legal requirements are met. The Report and the reported cases that include intellectual property elements clearly underscore that it is not the IPR system as such that is problematic. In fact, it is the opposite, competition issues originate from the unlawful conduct of pharmaceutical companies, which go against the objectives of the IPR system, for example, fraud on the patent office, vexatious litigation, or pay for delay settlement of patent disputes. European authorities have prosecuted a number of such cases, notably AstraZeneca, Lundbeck, Servier, Pfizer, Boehringer / Almirall etc, all summarised in the report.

482. The Commission believes that vigilant enforcement is needed to prevent abusive anti-competitive practices in all sectors, including the pharmaceutical sector. To that end, EU competition authorities have the normal toolbox of competition policy remedies, in particular monetary fines.

483. However, it cannot be inferred that patenting, patent litigation or other IP-related conduct is generally problematic from the competition law perspective.

484. On the international level, the EU effectively cooperates with other national authorities, including many WTO Members, on competition policy and enforcement issues of mutual interest. EU cooperation with competition authorities takes place at two levels. First, the Commission discusses competition-related matters in various international fora, such as the International Competition Network (ICN), where excessive pricing was discussed during its annual conference in Portugal in 2017. ICN is an effective forum with a broad expert outreach and brings together competition authorities from more than 100 jurisdictions, which exchange experiences and best practices in several meetings every year. Second, the Commission is also regularly engaged in bilateral cooperation, including in the pharmaceutical sector. The nature of the cooperation activity varies between countries and can cover cooperation on specific investigations, dialogue on competition policy issues as well as capacity building support.

485. Therefore, we remain to be convinced about the added value of discussing competition policy here at the TRIPS Council.

### **12.10 South Africa**

486. Competition law and policy is important first for the recognition and secondly the use and application of IPRs. I think that the discussion we had is indicative of the progress that we have made in the TRIPS Council. The very name of the division that is responsible for intellectual property at the WTO contains a reference to competition and so this makes it relevant to the discussions that we have in this meeting. The second point that we would like to make, given the different approaches that we see in respect of competition or anti-trust law enforcement, is that we recognize that these different approaches are legitimate policy choices that countries make.

487. In respect of the EU intervention, I would like to thank the distinguished delegate for the analysis and response to many issues that remain on the table and I think that the approach of the EU has demonstrated as an indicator to all of us that there is some sort of emerging communality in the way that we approach issues of competition and IP law in general.

## **13 INFORMATION ON RELEVANT DEVELOPMENTS ELSEWHERE IN THE WTO**

### **13.1 Dispute Settlement**

### **13.2 Amendment to the TRIPS Agreement**

### **13.3 IPR-Related Issues in Trade Policy Reviews**

#### **13.3.1 WTO Secretariat**

488. As on previous occasions, the Secretariat will provide a brief update of the IP policy issues that have come up in the most recent Trade Policy Reviews.

489. Since the last TRIPS Council Meeting in November 2018, the Trade Policy Reviews of the Armenia; Hong Kong, China; Nepal; and the United States have taken place. Of course, we will not attempt to summarize the full range of issues covered in each of these reviews; we will limit the update to those matters on which Members, including both developed and developing country Members, actively registered an interest by posing questions during the review process. The issues that were of particular interest in this concrete sense included:

- Domestic implementation of the TRIPS Agreement;
- Implementation of national intellectual property policies;
- Profit tax deductions for the purchase of IPRS;
- Contribution of intellectual property intensive industries to exports and imports;
- Copyright regimes, covering online and technological protection measures;
- Trademark regimes, including protection of well-known and unregistered trademarks, as well as requirements for prior use;
- Geographical indications regimes;
- Protection of industrial designs;
- Patent regimes, including projects to improve the efficiency and quality of the patent application and examination processes.
- Protection of undisclosed information and test data;
- Technology transfer policy, including projects to enhance innovation technology commercialization and partnerships;
- Governmental expenditures on research and development;
- Protection of trade secrets;
- Licensing and competition policy;
- Enforcement, civil remedies, criminal penalties online and at the border;
- Methodologies for calculating loss caused by infringements;
- Procedures for settling disputes, including mediation; and
- The Accession to, and implementation of, WIPO instruments.

490. Additionally, the Secretariat has contributed to the TRIPS-related section of the G20 and WTO-wide Director-General's Monitoring Reports, which were circulated to Members in late November 2018.

491. The section on "Policy Developments in Trade and Intellectual Property" in these reports highlights the trade-related IP policy initiatives undertaken by the Kingdom of Saudi Arabia and South Africa; as well as the information on developments in domestic legislation and administrative issues submitted for the monitoring exercise by Australia, Indonesia, the Kingdom of Saudi Arabia, Mexico and Turkey.

## **14 OBSERVER STATUS FOR INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS**

### **14.1 South Africa**

492. We would like to thank Members for the constructive debate that we have been able to have in this house recently. In particular, South Africa once again extends its congratulations to the Cooperation Council of the Arab States of the Gulf (GCC) for having been granted regular observer status.

493. Based on document IP/C/W/52/Rev.14, there are still several requests for observer status to the TRIPS Council that remain outstanding. South Africa supports the request that observer status be granted to the ACP Group, which represents 79 Members. There are 48 countries from Sub-Saharan Africa, 16 from the Caribbean and 15 from the Pacific. ACP Group's main objectives are sustainable development of its Members and their gradual integration into the global economy, which entails making poverty reduction a matter of priority and establishing a new, fairer, and more equitable world order. At the WTO the ACP remains an influential group and will greatly benefit from being granted observer status either on an *ad hoc* or permanent basis.

494. We also would like to reiterate previous calls for Members to agree on granting observer status to the South Centre and the Secretariat of the Convention on Biological Diversity (CBD).

### **14.2 Ecuador**

495. Ecuador continues to support the participation of the South Centre and the Secretariat of the Convention on Biological Diversity as WTO observers, or at least their participation as *ad hoc* observers.

### **14.3 United States of America**

496. The United States position has not changed. We cannot join the Members seeking to include these observers, either on a permanent or *ad hoc* basis.

497. The United States values the contributions of Members and is satisfied with the current set of *ad hoc* and permanent observers.

498. We do not see a gap that needs filling by adding new observers at this time. We also do not support ACP.

### **14.4 Venezuela, Bolivarian Republic of**

499. My delegation wishes to reiterate the statement it made at previous meetings of this Council, in which it expressed support for granting the South Centre observer status.

### **14.5 China**

500. China supports that the CBD Secretariat and South Centre should be granted observer status, at least on an *ad hoc* basis.

501. The relationship between TRIPS Agreement and CBD is an important issue in this Council, it is no doubt that CBD Secretariat has better understanding of specific rules and latest developments of

the CBD. China believes that the invitation to the CBD Secretariat as an observer will help Members better understand the CBD, thus promoting discussions and consultations on TRIPS/CBD.

502. South Centre plays an important role in strengthening the understanding and cooperation between developed and developing country Members, so as to push the discussion and consultation forward.

#### **14.6 Bangladesh**

503. On the observer status issue, the delegation of Bangladesh reiterates its position stated in the earlier meetings. We would like to support the South Centre to be granted observer status to this Council.

#### **15 OTHER BUSINESS**

504. No statements were made under this agenda item.

#### **16 ELECTION OF THE CHAIRPERSON**

505. No statements were made under this agenda item.

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